

## ***N*-methyl amisulpride (LB-102) Clinical Study Report**

### **Protocol LB-102-001**

#### **A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects**

Indication Studied:	LB-102 is indicated for the treatment of Schizophrenia
Developmental Phase of Study:	Phase 1
First Subject Enrolled:	06 January 2020
Last Subject Completed:	10 July 2020
Release Date of Report:	09 November 2020
Company/Sponsor Signatory:	LB Pharmaceuticals, Inc. 575 Madison Avenue New York, NY 10022 Telephone: 1 (646) 588-8175

This trial was conducted in accordance with the ethical principles of Good Clinical Practice, according to the ICH Harmonized Tripartite Guideline.

## 2. SYNOPSIS

**TITLE:** A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

**INVESTIGATIONAL PRODUCT:** LB-102 (*N*-methyl amisulpride)

**INDICATION:** LB-102 is indicated for the treatment of Schizophrenia

**PHASE OF DEVELOPMENT:** Phase 1

**INVESTIGATIONAL SITES/LOCATIONS:** Single US center

**OBJECTIVES:**

To evaluate the safety, tolerability, and pharmacokinetics (PK) of single (Part A - Single Ascending Dose (SAD)) and multiple (Part B - Multiple Ascending Doses (MAD)) oral doses of LB-102 compared to placebo.

**PRIMARY OBJECTIVE:**

Part A (SAD)

- To evaluate the safety and the tolerability of a single oral dose of LB-102 compared to placebo

Part B (MAD)

- To evaluate the safety and the tolerability of multiple oral doses of LB-102 compared to placebo

**SECONDARY OBJECTIVE:**

Part A (SAD)

- To evaluate the PK of a single dose of LB-102

Part B (MAD)

- To evaluate the PK of multiple oral doses of LB-102

**STUDY DESIGN:** This was a Phase 1, randomized double-blind, placebo-controlled study designed to evaluate the safety, tolerability, and PK of LB-102 in healthy subjects. The study consisted of two parts: Part A (SAD) and Part B (MAD). There were 5 cohorts in Part A and 3 cohorts in Part B. Each cohort consisted of 8 subjects (n = 6 assigned to LB-102 treatment, and n = 2 assigned to placebo treatment).

In Parts A and B, eligible subjects were randomized on Day 1 (pre-dose) to placebo (n=2) or LB-102 (n=6) treatment. Eligible subjects received 1 dose on Day 1 (Part A) or 13 doses on Days 1-7 (Part B) of placebo or LB-102. In Cohort 1 (Part A), dosing of the first 2 subjects (1 active and 1 placebo) commenced at least 24 hours prior to the remaining 6 subjects. Dosing of the remaining subjects in the cohort proceeded if no safety issues were identified for the first 2 subjects. Blood samples for PK and safety assessments were collected at nominal timepoints described below. Subjects were discharged on Day 3 (Part A) or Day 9 (Part B) and returned for a Follow-up Visit (Day 8 or Day 15, respectively) for safety review. For Cohort 5 (Part A), subjects returned for an additional Follow-up Visit.

The blinded available study results for a cohort were reviewed by a Safety Review Committee (SRC) and it was agreed whether the safety profile was sufficiently acceptable to support proceeding with the evaluation of the next higher dose level. The SRC was comprised of the Investigator, Medical Monitor, and a Sponsor Representative (voting members). Other non-voting consultants, including but not limited to, PK or medical expert, statistician, etc. may have supported the SRC on an as needed basis. Blinded data to be reviewed at the end of each cohort included but was not limited to adverse events (AEs), physical examinations, vital signs, 12-lead Electrocardiograms (ECGs), clinical laboratory safety tests, and concomitant medications/procedures. Blinded PK

analysis occurred at the end of each cohort (Cohorts 1-5) for the SAD study and after each cohort (Cohorts 6-8) for the MAD study.

Cohort	Part A
	Treatment
1 (n=8) <sup>a</sup>	LB-102 50 mg (n=6) or Matching Placebo (n=2) QD x 1 day
2 (n=8) <sup>b</sup>	LB-102 10 mg (n=6) or Matching Placebo (n=2) QD x 1 day
3 (n=8) <sup>b</sup>	LB-102 100 mg (n=6) or Matching Placebo (n=2) QD x 1 day
4 (n=8) <sup>b</sup>	LB-102 200 mg (n=6) or Matching Placebo (n=2) QD x 1 day
5 (n=8) <sup>b</sup>	LB-102 150 mg (n=6) or Matching Placebo (n=2) QD x 1 day
	Part B
6 (n=8)	LB-102 (n=6) 50 mg BID (100 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7)
	or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
7 (n=8)	LB-102 (n=6) 100 mg BID (200 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7)
	or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
8 (n=8)	LB-102 (n=6) 75 mg BID (150 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7)
	or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)

<sup>a</sup> For Cohort 1, the first 2 subjects were randomized to receive LB-102 (n=1) or placebo (n=1) at least 24 hours prior to the remaining 6 subjects.

<sup>b</sup> For Cohorts 2-5, the doses were allowed to be reduced based on the PK results of Cohort 1. Cohort 2 was reduced from 100 mg to 10 mg. Cohort 3 was reduced from 200 mg to 100 mg. Cohort 4 was reduced from 400 mg to 200 mg. Cohort 5 was reduced from 800 mg to 150 mg.

QD = Once daily; BID = Twice daily.

The doses do not increase in sequential order because the protocol allowed for dose adjustments. For example, dosage in Cohort 5 was reduced to 150 mg LB-102 QD after the SRC recommended to lower the planned dose following QTcF prolongation in Cohort 4 associated with 200 mg LB-102 QD. Dosage in Cohort 8 was reduced to 75 mg BID after the SRC recommended to lower the dose after 2 dystonia AEs occurred related to 100 mg LB-102 BID in Cohort 7.

**NUMBER OF SUBJECTS (PLANNED AND ANALYZED):** A total of 64 subjects were planned to be enrolled into the study with 8 subjects (6 active, 2 placebo) randomized for each of the 8 cohorts (exclusive of possible replacements). Subjects were considered enrolled when they were randomized to treatment.

## DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION:

### Key Inclusion Criteria:

Eligible subjects fulfilled the following inclusion criteria:

1. Competent to provide informed consent.
2. Voluntarily provide informed consent and Health Insurance Portability and Accounting Act (HIPAA) Authorization in accordance with local regulations and governing Institutional Review Board (IRB) requirements prior to any procedures or evaluations performed specifically for the sole purpose of the study.
3. Healthy adult male and female subjects between 18 to 55 years of age inclusive at the screening visit.
4. Body Mass Index (BMI)  $\geq 18$  and  $\leq 30$  kg/m<sup>2</sup> at screening visit.
5. Subjects must be in good general health as determined by medical history and physical examination with no clinically significant medical findings and no history of significant medical disease (e.g., cardiovascular, pulmonary, renal, etc.) or acute condition with the past 30 days.
6. Have normal clinical laboratory test results and ECG, which are not considered to be clinically significant by the Investigator.
7. Females participating in the study:

- a. Either must be of non-childbearing potential [surgically sterilized: hysterectomy, bilateral tubal ligation, salpingectomy, and/or bilateral oophorectomy at least 26 weeks before the Screening Visit] or postmenopausal. Menopause is defined as being amenorrhoeic for at least 2 years with plasma follicle-stimulating hormone (FSH) levels in the post-menopausal range at screening, based on the central laboratory's ranges; OR
  - b. Females of child-bearing potential must have a negative pregnancy test and be not breastfeeding at Screening and use either abstinence or an accepted contraception method during the treatment period and for an additional period of 30 days after the end of investigational treatment. For this study, accepted contraception methods include:
    - i. Condom plus spermicide
    - ii. Condom plus diaphragm
    - iii. Condom plus cervical cap or female condom
    - iv. Hormonal contraceptives
    - v. Intrauterine device
    - vi. Partner vasectomy and a use of barrier contraception methods
8. If male, subject must be surgically sterile or practicing at least 1 of the following methods of contraception, from initial study drug administration through 90 days after administration of the last dose of study drug:
  - a. Have had a vasectomy (at least 6 months earlier);
  - b. Use of a double-barrier contraception method, defined as male use of a condom and female use of a barrier method (e.g., contraceptive sponge, spermicidal jelly or cream with or without a diaphragm);
  - c. Partner use of hormonal contraceptives (oral, parenteral, vaginal, or transdermal) for at least 3 months prior to study drug administration;
  - d. Partner use of an intrauterine device;
  - e. Complete abstinence from sexual intercourse;
  - f. Male subjects not practicing complete abstinence must use a condom as a required form of birth control (in addition to at least 1 of the other methods listed above, if desired) in order to protect partners of male participants from exposure to study drug.
9. If male, subject must agree to abstain from sperm donation through 90 days after administration of the last dose of investigational drug.

**Key Exclusion Criteria:**

1. Are pregnant or lactating.
2. Have a history or presence of significant cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, or neurological disorders which, in the opinion of the Investigator, increases the risk of the study drug or may confound the interpretation of study measures.
3. Clinically significant abnormal findings on physical examination or vital signs.
4. History or presence of psychiatric or neurological disease or condition.
5. History of seizures.
6. Subject with any history or current evidence of suicidal behaviour.
7. Unwilling to complete any plan study assessments, including the Columbia-Suicide Severity Rating Scale (C-SSRS).
8. Recent history of alcohol or drug abuse (within the last two years).



9. Any use of tobacco or tobacco-containing products (cigarettes, pipes, etc.) within one month prior to Screening.
10. Have a history of blood donation in excess of 500 mL of blood within 30 days prior to Screening.
11. Have received treatment with an investigational drug or device within 60 days prior to Screening.
12. Use of any prescription or over the counter medication, herbal medications, vitamins, or supplements within 14 days prior to study drug administration.
13. Have a positive test for Human Immunodeficiency Virus (HIV) antibodies 1 and 2, Hepatitis B Surface Antigen (HBsAg) or Hepatitis C Virus (HCV) antibody.
14. Any subject who is known to be allergic to the drug or any components of the study drug.
15. The subject has a fasting blood glucose  $\geq 126$  mg/dL or hemoglobin A1c (HbA1c)  $\geq 6.5\%$  at Screening.
16. The subject has a history of QT prolongation or dysrhythmia or a family history of prolonged QT interval or sudden death.
17. Clinically significant abnormal finding on ECG and/or evidence of any of the following cardiac conduction abnormalities at Screening (ECG will be measured once in Part A for Cohorts 1-4. ECG will be measured in triplicate in Part A for Cohort 5 and Part B, mean values will be used for the following criteria):
  - a. Heart rate  $< 40$  bpm and  $> 100$  bpm (based on the ECG reading)
  - b. QTcF interval  $> 450$  msec for males and females
  - c. PR interval  $\geq 200$  msec
  - d. Intraventricular conduction delay with QRS duration  $> 120$  msec
  - e. Evidence of second or third-degree atrioventricular block (AVB)
  - f. Electrocardiographic evidence of complete left bundle branch block (LBBB)

**TEST PRODUCT(S), DOSE AND MODE OF ADMINISTRATION:** *N*-methyl amisulpride (LB-102) Powder in Capsule in dosage strengths of 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg, Oral administration.

**DURATION OF TREATMENT:** Part A: 1 day; Part B: 7 days.

**DISCONTINUATION FROM TREATMENT:**

Reasons for permanent discontinuation included the following:

- Any serious adverse event (SAE) regardless of association to LB-102 or placebo.
- Any  $\geq$  Grade 3 AE according to the appropriate toxicity grading scale. If a subject experienced an AE assessed as  $\geq$  Grade 3, that subject did not receive any additional doses and the subject was followed until the AE resolved or stabilized.
- Any other event that was deemed by the Investigator or Sponsor to pose an unacceptable risk to the subject.
- An increase in QTcF to  $> 500$  msec or  $> 60$  msec over baseline.
- Subject requested to discontinue treatment.

**CRITERIA FOR EVALUATION:**

**SAFETY:**

The following were assessed at pre-specified timepoints for safety measurements:

- AEs
- Hematology, chemistry, urinalysis
- Prolactin

- ECG
- Physical examination
- Vital signs
- C-SSRS

#### PHARMACOKINETICS:

PK parameters of LB-102 and amisulpride include maximum plasma concentrations ( $C_{\max}$ ), time to reach  $C_{\max}$  ( $T_{\max}$ ), area under the plasma concentration-time curve from 0 hours to a specified time ( $AUC_{0-t}$ ), area under the plasma concentration time curve from 0 hours to 24 hours ( $AUC_{0-24}$ ), area under the plasma concentration time curve from 0 hours to infinity ( $AUC_{0-\infty}$ ), area under the plasma concentration time curve extrapolated from specified time to infinity as a percentage of total AUC ( $AUC\%/_{\text{extrap}}$ ), apparent total clearance of the drug from plasma after oral administration ( $CL/F$ ), terminal rate constant ( $\lambda_z$ ), and elimination half-life ( $t_{1/2}$ ).

Plasma PK samples were obtained at the following nominal time points:

- Part A
  - Day 1: pre-dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  minutes) post-dose.
  - Days 2-3: 24, 32, and 48 hours ( $\pm 15$  minutes) post Day 1 dose.
  - Days 8 and 15 (For Cohort 5, Part A only).
- Part B
  - For Cohorts 6-7:
    - Day 1: prior to the first dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  minutes) post-dose.
    - Days 2-6: prior to first dose.
    - Day 7: pre-dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  minutes) post-dose.
    - Days 8-9: 24, 32, and 48 hours ( $\pm 15$  minutes) post Day 7 dose.
  - For Cohort 8 only:
    - Day 1: prior to the first dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  min) post first dose.
    - Days 2-5: prior to first dose.
    - Day 6: pre-dose, 15 and 30 minutes ( $\pm 5$  minutes), and 1, 2, 4, 8, 12, 12.25, 12.5, 13, 14, 16, 18, and 20 hours ( $\pm 15$  min) post dose.
    - Day 7: prior to first dose.
    - Days 8-9: 24, 32, and 48 hours ( $\pm 15$  min) post Day 7 dose.

#### STATISTICAL ANALYSIS:

##### SAFETY:

The statistical methods used were primarily descriptive and no formal statistical comparison of dose levels were made. The safety categorical variables were summarized using numbers and percentages. Continuous variables were summarized by total number (N), mean, standard deviation, median, minimum, and maximum. Each cohort was evaluated separately for safety. All placebo subjects from the different cohorts were combined into a single group for summary purposes.

A formal statistical analysis plan (SAP) was developed and finalized prior to unblinding the data. This plan defined populations for analysis, outlined all data handling conventions, and specified all statistical methods to be used for analysis of the data. A separate PK analysis plan was created.

Safety data, including vital signs, ECGs, laboratory test results, physical examinations, and AEs were summarized by dose and assessment time points, as appropriate. Change from baseline were included in the summary tables for laboratory, ECG, and vital sign parameters.

#### **PHARMACOKINETICS:**

Plasma concentrations of LB-102 and amisulpride were measured during the study and PK parameters derived using non-compartmental and/or compartmental methods as appropriate. No PK parameters were calculated for subjects with detectable concentrations for 2 or fewer time points.

Individual and mean plasma concentration time curves (both linear and log-linear) were included in the final report.

PK parameters of LB-102 and amisulpride were summarized by cohort using descriptive statistics (sample size, arithmetic means, geometric means, standard deviation, % coefficient of variation, minimum, median, and maximum). Figures were created to display mean and individual subject LB-102 and amisulpride concentration time curves in plasma on both a linear and logarithmic scale. Dose proportionality was assessed using a linear regression, or other acceptable approach.

#### **SAFETY PARAMETERS:**

Safety parameters include AEs, hematology, chemistry, urinalysis, prolactin, ECG, physical examination, vital signs, and C-SSRS.

#### **PHARMACOKINETIC PARAMETERS:**

For Part A (SAD), PK parameters of LB-102 and amisulpride include  $AUC_{0-t}$ ,  $AUC_{0-24}$ ,  $AUC_{0-inf}$ ,  $AUC_{\%/extrap}$ ,  $CL/F$ ,  $C_{max}$ ,  $T_{max}$ ,  $\lambda_z$ , and  $t_{1/2}$ .

For Part B (MAD), the individual concentration data before the second dose on Day 1 were used for PK parameter calculation. PK parameters included  $AUC_{0-12, D1}$ ,  $AUC_{0-24, D1}$ ,  $AUC_{0-inf, D1}$ ,  $AUC_{\%/extrap, D1}$ ,  $C_{max, D1}$ ,  $T_{max, D1}$ ,  $\lambda_{z, D1}$ , and  $t_{1/2, D1}$ . PK parameters of LB-102 and amisulpride were also calculated using the individual concentration profiles on Day 7-9, or by comparing the PK parameters on Day 1 with Day 7. PK parameters included  $AUC_{0-12, D7}$ ,  $AUC_{0-inf, D7}$ ,  $AUC_{extrap, D7}$ ,  $C_{max, D7}$ ,  $T_{max, D7}$ ,  $\lambda_{z, D7}$ ,  $t_{1/2, D7}$ ,  $R_{Cmax}$ ,  $R_{AUC}$ ,  $LI$ ,  $CL_{ss}/F$ , and  $\tau$ .

#### **SAFETY RESULTS:**

LB-102 was generally well-tolerated with all TEAEs either mild (37) or moderate (6) severity. Out of the 64 subjects, 28 subjects (50 mg QD, N=4; 10 mg QD, N=2; 100 mg QD, N=3; 200 mg QD, N=3; 150 mg QD, N=1; 50 mg BID, N=2; 100 mg BID, N=3; 75 mg BID, N=5; Placebo, N=5) experienced at least one TEAE, with a total of 43 TEAEs. Out of the 43 TEAEs, 29 (50 mg QD, 3; 10 mg QD, 1; 100 mg QD, 3; 200 mg QD, 5; 150 mg QD, 1; 50 mg BID, 2; 100 mg BID, 5; 75 mg BID, 8; Placebo, 1) were considered possibly, probably, or definitely related to treatment.

Of the TEAEs definitely related to study drug, there were 11 cases of elevated prolactin ( $\geq 100 \mu g/L$ ; 50 mg QD, N=3; 10 mg QD, N=1; 100 mg QD, N=1; 150 mg QD, N=1; 50 mg BID, N=2; 100 mg BID, N=1; 75 mg BID, N=2), 4 cases of moderate dystonia (200 mg QD, N=1; 100 mg BID, N=2; 75 mg BID, N=1), and 1 case of mild ECG QTcF prolongation (458 msec, 200 mg LB-102 QD) that were all resolved with either no course of action (prolactin increase and QTcF interval prolongation) or concomitant medications (dystonia). Due to 2 TEAEs in the same system organ class (acute dystonic reaction), treatment was halted in all subjects taking 100 mg LB-102 BID (Cohort 7) and the 2 subjects in Cohort 7 taking placebo. As a result, the SRC concluded to reduce the dose for Cohort 8 to 75 mg LB-102 BID. Additionally, because QTcF interval was fairly prolonged from pre-dose values (20-46 msec) in all subjects taking 200 mg LB-102 QD (Cohort 4), the dosage for Cohort 5 was reduced to 150 mg LB-102 QD. Of the TEAEs probably or possibly related to study drug, there were 4 cases of nausea (100 mg LB-102 QD, N=1; 200 mg LB-102, N=1; 100 mg LB-102 BID, N=1; 75 mg LB-102 BID, N=1) and 1 case of vomiting (100 mg LB-102 BID), urticaria (100 mg LB-102 QD), gastroesophageal disease (200 mg LB-102), insomnia (75 mg LB-102 BID), dizziness (75 mg LB-102 BID), and somnolence (75 mg LB-102 BID).

Vital signs and physical examination results were largely unchanged from baseline. Other than increases in prolactin, chemistry laboratory results were also relatively unchanged throughout study treatment. C-SSRS did not change during study treatment.

#### PHARMACOKINETICS RESULTS:

In Part A (SAD), LB-102 was rapidly absorbed and LB-102 concentration generally declined from peak in an apparent biphasic manner. The estimates of mean  $t_{1/2}$  of LB-102 generally ranged from 11.993 to 14.146 hours; exposure (as measured by  $C_{max}$ ,  $AUC_{0-t}$ , and  $AUC_{0-inf}$ ) increased in a slightly greater than dose-proportional manner. Mean  $C_{max}$  ranged from 24.1 ng/mL at the lowest dose of 10 mg LB-102 to 975.667 ng/mL at the highest dose of 200 mg LB-102. Mean  $AUC_{0-t}$  ranged from 221.911 h•ng/mL at the lowest dose to 6709.821 h•ng/mL at the highest dose. Mean  $AUC_{0-inf}$  ranged from 252.637 h•ng/mL at the lowest dose to 7002.109 h•ng/mL at the highest dose. Apparent clearance ( $CL/F$ ) appeared to decrease as dose increased (42.44 L/h to 28.89 L/h).

In Part A (SAD), amisulpride was formed quickly over time after a single dose of LB-102 (median  $T_{max}$  range = 2 to 3.5 hours) and generally declined with an approximate biphasic disposition of comparable shape to LB-102 but at approximately 2.5% of LB-102 abundance. The plasma concentrations of amisulpride at lower doses were within several fold of LLOQ making descriptive PK analysis tenuous. In fact, amisulpride was not detected in subjects taking 10 mg LB-102 QD (Cohort 2). Mean amisulpride  $t_{1/2}$  ranged from approximately 8.921 to 14.614 hours. Mean  $C_{max}$  ranged from 4.167 ng/mL at the lowest detectable dose, 50 mg LB-102, to 27.747 ng/mL at the highest dose, 200 mg LB-102. Mean  $AUC_{0-t}$  ranged from 31.183 h•ng/mL at the lowest detectable dose, 50 mg LB-102, to 247.397 h•ng/mL at the highest dose, 200 mg LB-102. Mean  $AUC_{0-inf}$  ranged from 188.552 h•ng/mL at the lowest detectable dose, 100 mg LB-102, to 314.264 h•ng/mL at the highest dose, 200 mg LB-102.

In Part B (MAD), extensive PK sampling occurred on Day 6 rather than Day 7 and the last dose was given on Day 7. Thus, the PK profile for the second dose on Day 6 (including the pre-dose on Day 7) was used to calculate the PK parameter after multiple doses. For the calculation of  $AUC_{0-12, D1}$ , the actual time for the 12-hour sample was used in place of the nominal 12 hour since the concentration at 12 hours post-dose could not be predicted.

In Part B (MAD), trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4. After multiple doses, there was slight to moderate accumulation of LB-102 across dose levels with mean accumulation ratio based on  $C_{max}$  after the first dose and last dose ( $R_{Cmax}$ ) values ranged from 1.121 to 1.798 and with mean  $RAUC$  values ranged from 1.472 to 1.925. Amisulpride had a higher accumulation than LB-102 across dose levels with mean  $R_{Cmax}$  values ranged from 1.317 to 2.016 and with mean  $RAUC$  values ranged from 1.801 to 2.232. Exposure (as measured by  $C_{max, D7}$  and  $AUC_{0-12, D7}$ ) to LB-102 increased in a dose proportional manner. Apparent clearance at steady state ( $CL_{ss}/F$ ) to LB-102 appeared to be similar as dose increased.

#### SUMMARY – CONCLUSIONS:

LB-102 was well-tolerated with all TEAEs either mild or moderate severity. The most notable safety result was mildly elevated prolactin levels, which was expected to occur based on LB-102's mechanism of action as a dopamine antagonist and that it is a commonly reported AE for drugs of this class ([Haddad and Wieck, 2004](#)). At the highest dose (200 mg LB-102), QTcF prolongation was a concern as well as acute dystonic reaction in 200 mg LB-102 QD and 75-100 mg LB-102 BID. There were no significant TEAEs at the lower doses.

For PK results in Part A (SAD), LB-102 was rapidly absorbed and LB-102 concentration generally declined from peak in an apparent biphasic manner. Exposure increased in a slightly greater than dose-proportional manner. Apparent clearance appeared to decrease as dose increased. Amisulpride was formed quickly over time after a single dose of LB-102 and generally declined with an approximate biphasic disposition of comparable shape to LB-102 but at approximately 2.5% of LB-102 abundance. The plasma concentrations of amisulpride at lower doses were within several fold of LLOQ making descriptive PK analysis tenuous. In fact, amisulpride was not detected in subjects taking 10 mg LB-102 QD (Cohort 2). In vitro studies suggest equal pharmacological potency between LB-102 and amisulpride, but since amisulpride is present at 2.5% LB-102 concentration, it thus represents a minor active metabolite (defined as either less than 10% parent concentration or less than 10% of total pharmacological activity).

For PK results in Part B (MAD), trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4. After multiple doses, there was slight to moderate accumulation of LB-102 across dose levels.

Amisulpride had a higher accumulation than LB-102 across dose levels. Exposure to LB-102 increased in a dose proportional manner. Apparent clearance at steady state to LB-102 appeared to be similar as the dose increased.

LB-102 was designed to be an improved version of amisulpride by having increased permeability across the blood-brain-barrier, which would potentially decrease the plasma concentrations needed to achieve efficacy. This would thereby decrease the magnitude and frequency of AEs typically observed in schizophrenia patients treated with amisulpride. The maximum tolerated dose of LB-102 was identified as 150 mg per day as either 150 mg QD or 75 mg BID. LB-102-001 achieved its objectives of identifying the safety, tolerability, and PK of a single oral dose and multiple oral doses of LB-102 in healthy subjects.

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#### 4. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

The following abbreviations and specialist terms are used in this study report.

Abbreviation or Specialist Term	Explanation
AE	Adverse Event
API	Active Pharmaceutical Ingredient
AUC <sub>%/extrap</sub>	Area under plasma concentration time curve extrapolated from specific time to infinity as a percentage of total AUC
AUC <sub>0-24</sub>	Area under the plasma concentration time curve from 0 hours to 24 hours
AUC <sub>0-inf</sub>	Area under the plasma concentration time curve from 0 hours to infinity
AUC <sub>0-t</sub>	Area under the plasma concentration time curve from 0 hours to a specified time
AVB	Atrioventricular Block
BID	Twice a Day
BLQ	Below Lower Limit of Quantification
BMI	Body Mass Index
CL	Corpora Lutea
CL/F	Apparent total drug clearance from plasma after oral administration
CL <sub>ss</sub> /F	Apparent Clearance at Steady State
C <sub>max</sub>	Maximum plasma concentration
CNS	Central Nervous System
CRF	Case Report Form
CRO	Contract Research Organization
CSR	Clinical Study Report
C-SSRS	Columbia-Suicide Severity Rating Scale
D <sub>2</sub>	Dopamine (D <sub>2</sub> ) Receptors
DM	Data Management

<b>Abbreviation or Specialist Term</b>	<b>Explanation</b>
DMP	Data Management Plan
ECG	Electrocardiogram
EDC	Electronic Data Capture
EPS	Extrapyramidal Side Effects
eCRF	electronic Case Report Form
FDA	US Food and Drug Administration
FGA	First Generation Antipsychotics
FSH	Follicle-Stimulating Hormone
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HbA1c	Hemoglobin A1c
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HED	Human Equivalent Doses
HIPAA	Health Insurance Portability and Accounting Act
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Institutional Review Board
LBBB	Left Bundle Branch Block
LCRA	Lead Clinical Research Associate
LLOQ	Lower Limit of Quantification
LI	Linearity Index
MAD	Multiple Ascending Doses
MedDRA	Medical Dictionary for Regulatory Activities
NOAEL	No-Observed-Adverse-Effect-Level
OAE	Other Significant Adverse Event

Abbreviation or Specialist Term	Explanation
PI	Principal Investigator The investigator who leads the study conduct at an individual study center. Every study center has a principal investigator.
PK	Pharmacokinetics
PO	Oral/by mouth
QD	Once Daily
R <sub>AUC</sub>	Accumulation ratio based on AUC after the first dose and last dose
RBBB	Right Bundle Branch Block
R <sub>Cmax</sub>	Accumulation ratio based on C <sub>max</sub> after the first dose and last dose
SAD	Single Ascending Dose
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SGA	Second Generation Antipsychotics
SRC	Safety Review Committee
SOC	System Organ Class
t <sub>1/2</sub>	Elimination half-life
T <sub>max</sub>	Time to reach maximum concentration
TEAE	Treatment-Emergent Adverse Event
λ <sub>z</sub>	Terminal rate constant



## **5. ETHICS**

### **5.1 Institutional Review Board (IRB)**

A valid IRB reviewed and approved the protocol, the investigator's informed consent form (ICF), and related subject information and recruitment materials before the start of the study. Protocol amendments and any updates to the ICF or other written materials given to subjects were reviewed and approved by the IRB. The IRB and contact information are included in this study report.

### **5.2 Ethical Conduct of the Study**

This trial was designed and monitored in accordance with Sponsor procedures, which comply with the ethical principles of Good Clinical Practice (GCP) as required by the major regulatory authorities, and in accordance with the Declaration of Helsinki.

### **5.3 Subject Information and Consent**

The investigator ensured that informed consent was obtained from the subject before any activity or procedure was undertaken that was not part of routine care. Subjects were given a thorough explanation of the objectives, procedures, benefits, potential risks, and any other detail about the study that would affect their decision to participate.

It was explained that participation was completely voluntary and subjects could refuse to enroll in the study or withdrawal at any time without needing to justify their decision and without affecting the benefits they are entitled to including further clinical care.

The subject received a signed copy of the signed ICF.

The subject was informed that any new information available that may be relevant to their willingness to continue participating in the study would be given to them.

Subjects were informed that a study monitor may review their medical records and data related to the study in accordance with applicable regulatory requirements. Confidentiality and data protection were handled in compliance with local laws.

## 6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

STUDY TITLE:	A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects.
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## 7. INTRODUCTION

### 7.1 Background and Rationale

Schizophrenia is a chronic and debilitating mental illness that affects approximately one percent of the population. Schizophrenia manifests in delusional behavior, dysfunctional thinking, agitated body movement, social withdrawal, and depression. Schizophrenia patients suffer a profoundly reduced quality of life and are ten times more likely to commit suicide than the general population ([Harris and Barraclough, 1997](#)). Half of suicides among patients with schizophrenia occur within the first two years of disease onset ([Tandon and Jibson, 2003](#)), pointing to the urgency for behavioral and pharmaceutical intervention.

There are at least 22 drugs (both first- and second-generation antipsychotics) approved by the US Food and Drug Administration (FDA) indicated for the treatment of schizophrenia ([HHS, 2012](#); [FDA, 2015](#)). Despite a seeming surfeit of available drugs to treat schizophrenia, adequate treatment of schizophrenia remains a challenge. Non-adherence and discontinuation of treatment is a major issue. A review of randomized, double-blind clinical trials involving schizophrenia or related disorders found that 53% of patients stopped their treatment at an early stage and the most prevalent reasons were poor response or psychiatric symptom worsening ([Liu-Seifert et al., 2005](#)). Discontinuation of treatment significantly increases the chance of relapse with estimated relapse rates of approximately 80% and 95% after discontinuing treatment for 12 and 24 months, respectively ([Emsley et al., 2013](#)).

Schizophrenia is a lifelong disease for the majority of patients. The course of schizophrenia is highly variable with periods of psychosis and stabilization of varying duration and intensity. Sustained remission of both positive and negative symptoms occurs in a minority of patients even with prolonged antipsychotic therapy. It is common for patients to have little or no response to an individual antipsychotic, necessitating the many therapeutic options currently available. Many patients, even when stable, suffer disability due to the cognitive and social deficits that occur despite adequate antipsychotic therapy. Compliance with long-term medication is a significant problem due to dissatisfaction with antipsychotic side effects, or self-discontinuation of medication as a result of feeling better and no longer perceiving the need for continuous medication. Both of these issues contribute to relapse among schizophrenia patients.

The standard pharmacologic mechanism of action for antipsychotic drugs is antagonism of dopamine (D<sub>2</sub>) receptors in the limbic system of the brain ([Meltzer and Stahl, 1976](#); [Joyce and Meador-Woodruff, 1997](#); [Wulff et al., 2015](#)). This has remained largely unchanged since antipsychotics began use clinically in the 1950s. Second Generation Antipsychotics (SGAs), also known as Atypical Antipsychotics, are preferred by patients and clinicians, and are used in the majority of patients. Older antipsychotics developed between 1950 and 1980 are referred to as first Generation Antipsychotics (FGAs) and are used primarily when patients have failed numerous SGAs. The primary advantage of SGAs is a lower incidence of Extrapyramidal Side Effects (EPS) that resemble the types of movement disorders that occur in Parkinson's disease. Patients who experience EPS from a specific antipsychotic will often ask for a different drug or discontinue on their own. While SGAs were an important advance, these drugs are not free of the common side effects of many Central Nervous System (CNS) drugs that arise from varying degrees of antagonism of dopamine, histamine, serotonin, muscarinic, hERG, and alpha receptors. Further,

these drugs distribute widely throughout the CNS due to their ability to easily cross the blood brain barrier by passive diffusion allowing off-target effects to occur. SGA side effects as a result of off-target receptor engagement include weight gain, elevations in lipids and blood sugar, sedation, dry mouth, constipation, dizziness and falls due to low blood pressure, QT interval prolongation, cognitive impairment, and prolactin elevation. Until a disease modifying therapy is developed for schizophrenia, the ideal antipsychotic would be a drug that has selectivity for the limbic system and minimal to no engagement of receptors that cause side effects.

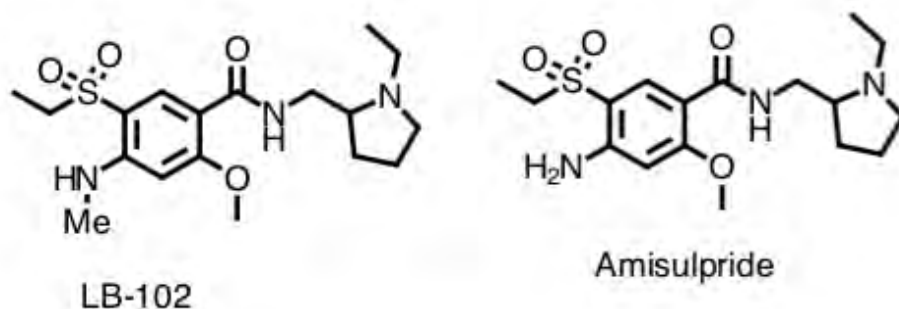
LB-102 was designed to be an improved version of the benzamide antipsychotic amisulpride having increased permeability across the blood-brain-barrier, potentially decreasing the plasma concentrations needed to achieve efficacy thereby decreasing the magnitude and frequency of Adverse Events (AEs) typically observed in patients treated with amisulpride.

Amisulpride, originally developed in France in the 1980s ([Thominet et al., 1983](#)), is approved in more than 50 countries worldwide for the treatment of schizophrenia and in certain countries for the treatment of dysthymia ([IMS, 2015](#)). Amisulpride elicits its activity in part by selectively blocking the human dopaminergic D<sub>2</sub> (K<sub>i</sub> 2.8 nM) and D<sub>3</sub> (K<sub>i</sub> 3.2 nM) receptor with negligible affinity for the D<sub>1</sub>, D<sub>4</sub>, and D<sub>5</sub> receptor subtypes (K<sub>i</sub> > 1,000 nM) and in part by its activity against the 5-HT<sub>7</sub> receptor (11.5 nM K<sub>i</sub>). While amisulpride is a clinically effective drug, it demonstrates poor distribution to the brain. A 2014 study ([Dos Santos Pereira et al., 2014](#)), revealed that passive diffusion of amisulpride across a PAMPA membrane was the lowest of 30 psychiatric drugs tested (Figure 1).

## 7.2 Description

LB-102 (Figure 1) was created by adding a methyl group to the aniline nitrogen of amisulpride. The molecular weight is 383.51.

**Figure 1: Structure of LB-102 and Amisulpride**



## 7.3 Nonclinical Pharmacology

### 7.3.1 Pharmacodynamics

In rodents, amisulpride preferentially blocks post-synaptic D<sub>2</sub> receptors in the limbic structures (responsible for affective and cognitive processes) preferentially over those in the striatum (responsible for extrapyramidal effects). In addition, amisulpride does not induce catalepsy and it does not produce D<sub>2</sub> hypersensitivity after repeated treatment. Amisulpride preferentially blocks pre-synaptic D<sub>2</sub>/D<sub>3</sub> dopamine receptors at low doses, producing the dopamine release that is responsible for its disinhibitory effects. In animal preclinical models of schizophrenia amisulpride has been demonstrated to mimic current antipsychotics in the amphetamine induced hyperactivity ([Perrault et al., 1997](#)) and conditioned avoidance response ([Natesan et al., 2008](#)) models.

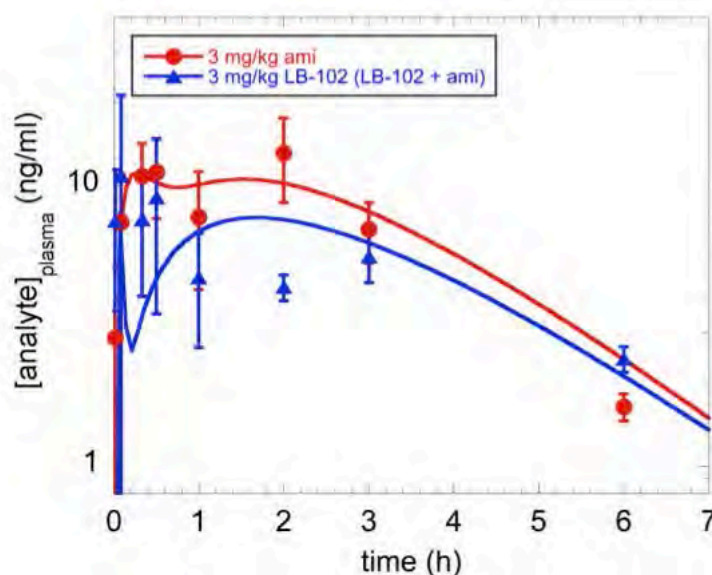
The pharmacodynamics of amisulpride is well-established ([Solian Label, 2019](#)), and based on the physicochemical attributes of LB-102 measured to date suggest they will be similar.

### 7.4 Clinical Experience and Pharmacokinetics

LB Pharmaceuticals, Inc. has not conducted any studies of LB-102 in humans, however pharmacokinetic (PK) data from prior studies in mice, rats, and dogs have provided initial feedback on how the PK profile LB-102 compares to amisulpride.

A study was conducted to compare the PK of LB-102 to amisulpride in rats following a single oral dose of 3 mg/kg. The total plasma concentrations of benzamide, which includes LB-102 and its metabolite amisulpride, were found to be equivalent in LB-102- and amisulpride-treated rats (Figure 2).

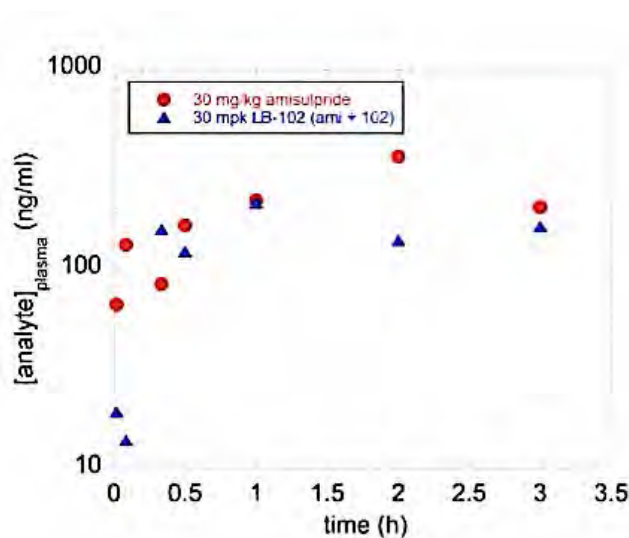
**Figure 2: Plasma Concentration vs. Time Curves Following Single Oral Dose of 3 mg/kg LB-102 (Exposures to Amisulpride Pluse LB-102) or Amisulpride (Exposures to Amisulpride) in Rats**



Ref: LB-102-001 Clinical Protocol (Version 6, 24 June 2020) [Section 3.4](#).

A PK study of LB-102 in mice was also conducted following a single oral dose of 30 mg/kg amisulpride or LB-102, and data for the total benzamide concentrations are depicted in Figure 3. In concordance with the PK data in rats, about 50% of LB-102 is metabolized into amisulpride and the total plasma concentration of benzamide after oral dosing LB-102 was consistent with that of amisulpride.

**Figure 3: PK Profile of Single Oral Dose of 30 mg/kg in Mice (n=3/group)**



Ref: LB-102-001 Clinical Protocol (Version 6, 24 June 2020) [Section 3.4](#).

Preliminary PK studies show that LB-102 behaves similarly to amisulpride in both mice and rats.

## 8. STUDY OBJECTIVES

### 8.1 Primary Objective

#### Part A Single Ascending Dose (SAD)

- To evaluate the safety and tolerability of a single oral dose of LB-102 compared to placebo.

#### Part B Multiple Ascending Doses (MAD)

- To evaluate the safety and tolerability of multiple oral doses of LB-102 compared to placebo.

### 8.2 Secondary Objective

#### Part A (SAD)

- To evaluate the PK of a single oral dose of LB-102.

#### Part B (MAD)

- To evaluate the PK of multiple oral doses of LB-102.

## 9. INVESTIGATIONAL PLAN

### 9.1 Overall Study Design and Plan: Description

This was a Phase 1, randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, and PK of LB-102 in healthy subjects. The study consisted of two parts: Part A – SAD and Part B – MAD. There were 5 cohorts in Part A and 3 cohorts in Part B of this study. The following schedule represented the ideal study schedule and was used as a guidance for the study conduct. In the event there were delays at any visit days that affected the dates of any subsequent visit, the planned days varied.

In Part A, eligible subjects, in 5 cohorts, were randomized on Day 1 (pre-dose) to placebo (n=2) or LB-102 (n=6) treatment for a total of 40 subjects. Four (4) visits occurred as follows: Screening (Visit 1, Days -28 to -1), Check-in (Visit 2, Day 0), Treatment Evaluation (Visit 3, Days 1-3), and Follow-up (Visit 4, Day 8 and Visit 5, Day 15 [for Cohort 5, Part A only]). The study procedures for these visits are presented in detail in [Table 2](#). Dosage of LB-102 began at 50 mg/day and subsequent groups were administered 10, 100, 200, and 150 mg/day, respectively. In Cohort 1 (Part A), dosing of the first 2 subjects (1 active and 1 placebo) commenced at least 24 hours prior to the remaining 6 subjects. Dosing of the remaining subjects in the cohort proceeded if no safety issues were identified for the first 2 subjects. On Day 1, following a 12-hour overnight fast, subjects received 1 oral dose of placebo or LB-102 at 8 AM ( $\pm 1$  hour). For each cohort, blood samples for PK were collected on Day 1 at pre-dose and at 15, 30, and 45 minutes ( $\pm 5$  min), and 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 32, and 48 hours ( $\pm 15$  min) post-dose, and Day 8 and Day 15. Vital signs were recorded for each subject at Screening, Check-in, Day 1 at pre-dose and at 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, and 48 hours ( $\pm 30$  min) post-dose, and at the Follow-up visit (Day 8). 12-lead ECG was done on at Screening, Check-in, Day 1 at pre-dose and 1, 2, 3, 4, 5, 6, 8 and 24 hours ( $\pm 30$  min) post-dose. ECG was measured once at each time point for Cohorts 1-4 and in triplicate for Cohort 5. Clinical labs (hematology, chemistry, urinalysis) were assessed at Screening, Check-in, Day 2, and Follow-Up. Hemoglobin A1c (HbA1c) was measured in serum at Screening. Prolactin was measured in serum at Screening, Day 3, Day 8, and Day 15. C-SSRS was assessed at Screening and Day 3. Subjects remained in the clinic from Check-in to Discharge on Day 3 for additional safety assessment and then returned for a Follow-up Visit on Day 8. Subsequent groups followed the same study procedures.

In Part B, eligible subjects, in 3 cohorts, were randomized on Day 1 (pre-dose) to placebo (n=2) or LB-102 (n=6) treatment for a total of 24 subjects. Four (4) visits were scheduled for this study: Screening (Visit 1, Days -28 to -1), Check-in (Visit 2, Day 0), Treatment Evaluation (Visit 3, Days 1-9), and Follow-up (Visit 4, Day 15). The study procedures for these visits are presented in detail in [Table 3](#). Dosage of LB-102 was based on the PK observed in a minimum of 2 Part A cohorts. Subjects received 2 doses of placebo or LB-102, first dose at 8:00 AM ( $\pm 1$  hour) and second dose approximately 12 hours later, on Days 1-6 and one dose at 8 AM ( $\pm 1$  hour) on Day 7 for a total of 13 oral doses. The first dose on Day 1 occurred following a 12 hour, overnight fast. For Cohort 6-7, blood samples for PK were collected at multiple timepoints starting on Day 1 at pre-dose and at 15, 30, and 45 minutes ( $\pm 5$  min), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  min) post first dose. On Days 2-6, blood samples for PK were collected prior to the first dose. On Day 7 blood samples for PK were collected pre-dose and at 15, 30, and 45 minutes ( $\pm 5$  min), and 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 32, and 48 hours ( $\pm 15$  min) post first dose. For Cohort 8, blood samples



for PK were collected at multiple timepoints starting on Day 1 at pre-dose and at 15, 30, and 45 minutes ( $\pm 5$  min), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  min) post first dose. On Days 2-5, blood samples for PK were collected prior to the first dose. On Day 6, blood samples for PK were collected pre-dose, at 15 and 30 minutes ( $\pm 5$  min), and 1, 2, 4, 8, 12, 12.25, 12.5, 13, 14, 16, 18, and 20 hours ( $\pm 15$  min) post dose. On Day 7, blood samples for PK were collected prior to first dose, 24 (Day 8), 32 (Day 8), and 48 (Day 9) hours ( $\pm 15$  min) post Day 7 dose. Vital signs were recorded for each subject at Screening, Check-in, Day 1 at pre-dose and at 0.5, 1, 1.5, 2, 4, 6, 8 and 12 hours ( $\pm 30$  min) post first dose on Day 1, at pre-dose and 2 hours ( $\pm 30$  min) post first dose on Days 2-7, 24 and 48 hours ( $\pm 30$  min) post Day 7 dose, and at Follow-up. 12-lead ECG was done in triplicate at Screening, Check-in, Day 1 at pre-dose and 1, 2, 3, 4, 5, 6, and 8 hours ( $\pm 30$  min) post first dose, prior to first dose on Days 2-7, and on Day 8 (24 hours ( $\pm 30$  min) post-dose Day 7). Clinical labs were assessed at Screening, Check-in, prior to first dose on Day 4, Day 8, and at Follow-up. HbA1c was measured in serum at Screening. Prolactin was measured in serum at Screening, Day 4, Day 9, and Day 15. C-SSRS was assessed at Screening, Day 4, and Day 8. Subjects remained in the clinic from Check-in to Discharge on Day 9 for additional safety assessment and then returned for a Follow-up Visit on Day 15. Subsequent groups followed the same study procedures.

When there were two or more procedures (ECG, vital signs, and PK) scheduled for the same timepoint, the procedures were as close to the time point as possible and in the following order: ECG, vital signs, and then PK blood collection.

The PK profile included maximum plasma concentrations ( $C_{\max}$ ), time to reach  $C_{\max}$  ( $T_{\max}$ ), area under the plasma concentration-time curve from 0 hours to a specified time ( $AUC_{0-t}$ ), area under the plasma concentration time curve from 0 hours to 24 hours ( $AUC_{0-24}$ ), area under the plasma concentration time curve from 0 hours to infinity ( $AUC_{0-\infty}$ ), area under the plasma concentration time curve extrapolated from specified time to infinity as a percentage of total AUC ( $AUC_{\%/extrap}$ ), apparent total clearance of the drug from plasma after oral administration ( $CL/F$ ), terminal rate constant ( $\lambda_z$ ), and elimination half-life ( $t_{1/2}$ ). PK samples were analyzed for all subjects in each cohort prior to dose escalation. These data were used as adjunct information for a safety review, which included a review of AEs, changes in vital signs, physical examination, and clinical laboratory test results.

If the starting dose (50 mg/day) for Cohort 1 (Part A) resulted in a total benzamide (LB-101 and LB-102) geometric mean  $C_{\max}$  greater than 175 ng/mL or a geometric mean of total benzamide exposure ( $AUC_{\infty}$ ) greater than 3,270 ng/mL\*h, the dose for Cohort 2 was adjusted downward, to the nearest 10 mg, by the equations below (equations are based on the observed PK and assume dose linearity). The equation producing the lower dose was selected. If the terminal phase PK was not captured adequately by the last time point collection, time was extended to capture at least 2 time points of the terminal phase. Upon collection of the PK from Cohort 2, the human PK model incorporated the human PK data and any elements of non-dose-linear PK. Dosing of the 3rd cohort resumed at 100 mg unless there was a clinical concern with safety in Cohort 2. If there was a clinical concern in Cohort 2, the SRC convened and determined an appropriate dose for Cohort 3. Dose escalation was designed to at least capture the exposure range listed in [Table 1](#) with the intent to exceed a  $C_{\max}$  of 1,200 ng/mL and or an  $AUC_{\infty}$  of 16,000 ng/mL\*h unless there were clinical



findings limiting further escalation. Dose escalation to 200 mg in Cohort 4 and 400 mg in Cohort 5 were dependent on clinical observations.

$$\text{Dose 2} = 50 \text{ mg} * C_{\text{max}} 35 \text{ ng/mL} / \text{Observed } C_{\text{max}} (\text{ng/mL})$$

or

$$\text{Dose 2} = 50 \text{ mg} * \text{AUC}_{\text{inf}} 655 \text{ ng/mL*h} / \text{Observed } \text{AUC}_{\text{inf}} (\text{ng/mL*h})$$

**Table 1: Target  $C_{\text{max}}$  and  $\text{AUC}_{\text{inf}}$  for Total Benzaminde Plasma Concentration Resulting from Dosing LB-102**

<b>Dose (mg)</b>	<b><math>C_{\text{max}}</math> (ng/ml)</b>	<b><math>\text{AUC}_{\text{inf}}</math> (ng/ml*h)</b>
10	35	330
50	173	1648
100	346	3297
200	692	6593
400	1384	13186

A Safety Review Committee (SRC) was assembled to review the blinded available study results for a cohort and agree whether the safety profile was sufficiently acceptable to support proceeding with the evaluation of the next higher dose level. The SRC was comprised of the Investigator, Medical Monitor, and a Sponsor Representative (voting members). Other non-voting consultants, including but not limited to, PK or medical expert, statistician, etc. may have supported the SRC on an as needed basis. Blinded data to be reviewed after each cohort included, but was not limited to AEs, physical examinations, vital signs, 12-lead ECGs, clinical laboratory safety tests, and concomitant medications/procedures. Blinded PK analysis occurred at the end of each cohort (Cohorts 1-5) for the SAD study and after each cohort (Cohorts 6-8) for the MAD study.

**Table 2: Study Design and Schedule of Assessments for Part A**

Visit	Screening	Check-In	Treatment Evaluation			Follow-Up
	1	2	3			4 and 5
Days	Days -28 to -1	Day 0	Day 1	Day 2	Day 3	Days 8 and 15 <sup>9</sup>
Informed Consent	X					
Inclusion/Exclusion Criteria	X	X				
Medical History	X	X				
Demographics	X					
Randomization			X			
Height, Weight, BMI <sup>1</sup>	X					X (Day 8 only)
Physical Examination	X	X		X		X (Day 8 only)
Vital Signs <sup>2</sup>	X	X	X	X	X	X (Day 8 only)
Laboratory Tests	X	X		X		X (Day 8 only)
Serum HbA1c	X					
Serum Prolactin	X				X	X
HIV, HBsAg, and HCV Labs	X					
12-Lead ECG <sup>3</sup>	X	X	X	X		
C-SSRS	X				X	
Urine Drug Screening	X	X				
Alcohol Breathalyzer	X	X				
Pregnancy <sup>4</sup>	X	X				X (Day 8 only)
FSH <sup>5</sup>	X					
Plasma PK <sup>6</sup>			X	X	X	X
Dose Subjects <sup>7</sup>			X			
Concomitant Medication <sup>8</sup>	X	X	X	X	X	X
AE Assessment <sup>8</sup>		X	X	X	X	X

BMI = Body Mass Index; C-SSRS = Columbia-Suicide Severity Rating Scale; ECG = Electrocardiogram; FSH = Follicle-Stimulating Hormone; HbA1c = Hemoglobin A1c; HBsAg = Hepatitis B Surface Antigen; HCV = Hepatitis C Virus; HIV = Human Immunodeficiency Virus; PK = Pharmacokinetic

<sup>1</sup> Only Weight was recorded at Follow-up, height and BMI were not.

<sup>2</sup> Vital Signs were measured at Screening, Check-in, Day 1 at pre-dose and 0.5, 1, 1.5, 2, 4, 6, 8, 12, 24, and 48 (±30 min) hours post-dose, and at Follow-up (Day 8).

<sup>3</sup> ECG was measured at Screening, Check-in, Day 1 at pre-dose and 1, 2, 3, 4, 5, 6, 8, and 24 (±30 min) hours post-dose. ECG was measured once at each time point for Cohorts 1-4 and in triplicate (approximately 1 min apart) for Cohort 5.

<sup>4</sup> Serum pregnancy test at Screening and Urine pregnancy test at Day 0 and Day 8 for all females of childbearing potential.

<sup>5</sup> FSH test for postmenopausal women.

<sup>6</sup> Plasma PK samples were collected on Day 1 at pre-dose, 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 32, and 48 hours (±15 min) postdose, and Days 8 and 15.

<sup>7</sup> Subjects were required to fast for approximately 12 hours prior to Day 1 dosing.

<sup>8</sup> Concomitant Medication and AE Assessment were recorded once per day on the days indicated.

<sup>9</sup> Day 15 Follow-Up Visit was scheduled for Cohort 5, Part A only.

**Table 3: Study Design and Schedule of Assessments for Part B**

Visit	Screening	Check-In	Treatment Evaluation			Follow-Up
Days	1	2	3			4
	Days -28 to -1	Day 0	Day 1	Days 2-7	Days 8-9	Day 15
Informed Consent	X					
Inclusion/Exclusion Criteria	X	X				
Medical History	X	X				
Demographics	X					
Randomization			X			
Height, Weight, BMI <sup>1</sup>	X					X
Physical Examination	X	X		X (Days 2, 4 only)	X (Day 8 only)	X
Vital Signs <sup>2</sup>	X	X	X	X	X	X
Laboratory Tests	X	X		X (Day 4 only)	X (Day 8 only)	X
Serum HbA1c	X					
Serum Prolactin	X			X (Day 4 only)	X (Day 9 only)	X
HIV, HBsAg, and HCV Labs	X					
12-Lead ECG <sup>3</sup>	X	X	X	X	X (Day 8 only)	
C-SSRS	X			X (Day 4 only)	X (Day 8 only)	
Urine Drug Screening	X	X				
Alcohol Breathalyzer	X	X				
Pregnancy <sup>4</sup>		X	X			X
FSH <sup>5</sup>		X				
Plasma PK <sup>6</sup>			X	X	X	
Dose Subjects <sup>7</sup>			X	X		
Concomitant Medication <sup>8</sup>	X	X	X	X	X	X
AE Assessment <sup>8</sup>		X	X	X	X	X

BMI = Body Mass Index; C-SSRS = Columbia-Suicide Severity Rating Scale; ECG = Electrocardiogram; FSH = Follicle-Stimulating Hormone; HbA1c = Hemoglobin A1c; HBsAg = Hepatitis B Surface Antigen; HCV = Hepatitis C Virus; HIV = Human Immunodeficiency Virus; PK = Pharmacokinetic

<sup>1</sup> Only Weight was recorded at Follow-up, height and BMI were not.

<sup>2</sup> Vital Signs were measured at Screening, Check-in, Day 1 at pre-dose and 0.5, 1, 1.5, 2, 4, 6, 8, and 12 (±30 min) hours post first dose, prior to the first dose and 2 hours (±30 min) post first dose on Days 2-7, 24, and 48 hours (±30 min) post Day 7 dose, and at Follow-up.

<sup>3</sup> ECG was measured in triplicate at Screening, Check-in, Day 1 prior to the first dose and 1, 2, 3, 4, 5, 6, and 8 hours (±30 min) hours post first dose, prior to first dose on Days 2-7, and Day 8 (24 hours (±30 min) post Day 7 dose).

<sup>4</sup> Serum pregnancy test at Screening and Urine pregnancy test at Day 0 and Day 15 for all females of childbearing potential.

<sup>5</sup> FSH test for postmenopausal women.

<sup>6</sup> For Cohort 6-7, plasma PK samples were collected on Day 1 prior to the first dose, and 15, 30, and 45 minutes (±5 minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours (±15 min) post first dose, Days 2-6: prior to first dose, Day 7 prior to the first dose and 15, 30, and 45 minutes (±5 min), and 1, 1.5, 2, 3, 4, 6, 8, 12, 16, 24, 32, and 48 hours (±15 min) post first dose.

For Cohort 8 only, plasma PK samples will be collected on Day 1 prior to the first dose and 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12 and 16 hours ( $\pm 15$  min) post first dose, Days 2-5: prior to first dose, Day 6 prior to the first dose, 15 and 30 minutes ( $\pm 5$  minutes), and 1, 2, 4, 8, 12, 12.25, 12.5, 13, 14, 16, 18, and 20 hours ( $\pm 15$  min) post dose. On Day 7, blood samples for PK will be collected prior to first dose, 24 (Day 8), 32 (Day 8), and 48 (Day 9) hours ( $\pm 15$  min) post Day 7 dose.

<sup>7</sup> Subjects were required to fast for approximately 12 hours prior to the first Day 1 dose. On Days 1-6, subjects received 2 doses per day (8 AM and 8 PM  $\pm 1$  hour) separated by approximately 12 hours. On Day 7, subjects received 1 dose (8 AM  $\pm 1$  hour).

<sup>8</sup> Concomitant Medication and AE Assessment were recorded once per day on the days indicated.

## **9.2 Discussion of the Study Design, Including the Choice of Control Groups**

The randomization of subjects to active treatment or placebo in small cohorts along with the review of data between each cohort ensured that dose escalation occurred safely and efficiently.

## **9.3 Selection of Study Population**

### **9.3.1 Inclusion Criteria**

For inclusion into the trial, subjects were required to fulfill all of the following criteria:

- Competent to provide informed consent.
- Voluntarily provided informed consent and Health Insurance Portability and Accounting Act (HIPAA) Authorization in accordance with local regulations and governing IRB requirements prior to any procedures or evaluations performed specifically for the sole purpose of the study.
- Healthy adult male and female subjects between 18 to 55 years of age inclusive at the screening visit.
- Body Mass Index (BMI)  $\geq 18$  and  $\leq 30$  kg/m<sup>2</sup> at screening visit.
- Subjects were in good general health as determined by medical history and physical examination with no clinically significant medical findings and no history of significant medical disease (e.g., cardiovascular, pulmonary, renal, etc.) or acute condition within the past 30 days.
- Have had normal clinical laboratory test results and ECG, which were not considered to be clinically significant by the Investigator.
- Females participating in the study:
  - a. Either must have been of non-childbearing potential [surgically sterilized: hysterectomy, bilateral tubal ligation, salpingectomy, and/or bilateral oophorectomy at least 26 weeks before the Screening Visit] or postmenopausal. Menopause was defined as being amenorrhoeic for at least 2 years with plasma follicle-stimulating hormone (FSH) levels in the post-menopausal range at screening, based on the central laboratory's ranges; OR
  - b. Females of child-bearing potential must have had a negative pregnancy test and be not breastfeeding at Screening and use either abstinence or an accepted contraception method during the treatment period and for an additional period of 30 days after the end of investigational treatment. For this study, accepted contraception methods included:

- condom plus spermicide
  - condom plus diaphragm
  - condom plus cervical cap or female condom
  - hormonal contraceptives
  - intrauterine device
  - partner vasectomy and a use of barrier contraception methods
- If male, subject was surgically sterile or practicing at least 1 of the following methods of contraception, from initial study drug administration through 90 days after administration of the last dose of study drug:
  - a. Have had a vasectomy (at least 6 months earlier);
  - b. Use of a double-barrier contraception method, defined as male use of a condom and female use of a barrier method (e.g., contraceptive sponge, spermicidal jelly or cream with or without a diaphragm);
  - c. Partner use of hormonal contraceptives (oral, parenteral, vaginal, or transdermal) for at least 3 months prior to study drug administration;
  - d. Partner use of an intrauterine device;
  - e. Complete abstinence from sexual intercourse;
  - f. Male subjects not practicing complete abstinence must have used a condom as a required form of birth control (in addition to at least 1 of the other methods listed above, if desired) in order to protect partners of male participants from exposure to study drug.
- If male, subject must have agreed to abstain from sperm donation through 90 days after administration of the last dose of investigational drug.

### 9.3.2 Exclusion Criteria

Any of the following was regarded as a criterion for exclusion from the trial:

1. Were pregnant or lactating.
2. Had a history or presence of significant cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, or neurological disorders which, in the opinion of the Investigator, increases the risk of the study drug or may have confounded the interpretation of study measures.
3. Clinically significant abnormal findings on physical examination or vital signs.

4. History or presence of psychiatric or neurological disease or condition.
5. History of seizures.
6. Subject with any history or current evidence of suicidal behavior.
7. Unwilling to complete any planned study assessments, including the Columbia-Suicide Severity Rating Scale (C-SSRS).
8. Recent history of alcohol or drug abuse (within the last two years).
9. Any use of tobacco or tobacco-containing products (cigarettes, pipes, etc.) within one month prior to Screening.
10. Had a history of blood donation in excess of 500 mL of blood within 30 days prior to Screening.
11. Had received treatment with an investigational drug or device within 60 days prior to Screening.
12. Used any prescription or over the counter medication, herbal medications, vitamins, or supplements within 14 days prior to study drug administration.
13. Had a positive test for Human Immunodeficiency Virus (HIV) antibodies 1 and 2, Hepatitis B Surface Antigen (HBsAg) or Hepatitis C Virus (HCV) antibody.
14. Any subject who was known to be allergic to the study drug or any components of the study drug.
15. The subject had a fasting blood glucose  $\geq 126$  mg/dL or HbA1C  $\geq 6.5\%$  at Screening.
16. The subject had a history of QT prolongation or dysrhythmia or a family history of prolonged QT interval or sudden death.
17. Clinically significant abnormal finding on ECG and/or evidence of any of the following cardiac conduction abnormalities at Screening (ECG will be measured once in Part A for Cohorts 1-4. ECG were measured in triplicate in Part A for Cohort 5 and Part B, mean values will be used for the following criteria):
  - a. Heart rate  $< 40$  bpm and  $> 100$  bpm (based on the ECG reading)
  - b. QTcF interval  $> 450$  msec for males and females
  - c. PR interval  $\geq 200$  msec
  - d. Intraventricular conduction delay with QRS duration  $> 120$  msec
  - e. Evidence of second- or third-degree atrioventricular block (AVB)

- f. Electrocardiographic evidence of complete left bundle branch block (LBBB), complete right bundle branch block (RBBB), or incomplete LBBB

### **9.3.3 Removal of Subjects from Therapy or Assessment**

All subjects were free to withdraw from participation in this study at any time for any reason and without prejudice.

If a subject was withdrawn from dosing before completing the study, the reason for withdrawal was entered on the appropriate case report form (CRF). Whenever possible and reasonable, evaluations that were scheduled for study completion were performed at the time of premature discontinuation of dosing.

Subjects who discontinued from the study may have been replaced at the discretion of the sponsor.

Additional subjects were screened as reserve subjects for each cohort. Reserve subjects who were eligible for enrollment were also admitted to the clinical unit to ensure enough eligible subjects were available to fill the cohort. Subjects who fulfilled the eligibility criteria but were not randomized may have either remained at the clinical unit for participation on a subsequent dosing date or they may have been discharged and returned for a future dosing date. Check-In (Day 0) procedures did not need to be repeated if the subject remained confined to the clinical unit and protocol restrictions were monitored and followed. If the subject was discharged and returned, Check-In procedures were repeated. Subjects fulfilling the entry criteria and not randomized may have been admitted to the Phase 1 Unit for participation in a subsequent cohort so long as they remained within the 28-day screening period. Subjects who fell outside the 28-day Screening period were allowed to rescreen.

## **9.4 Treatments**

### **9.4.1 Treatments Administered**

For Part A of the protocol, subjects were dispensed either a LB-102 capsule or matching placebo based on their assigned treatment at 8 AM ( $\pm 1$  hour) after fasting for approximately 12 hours. Subjects took the capsule orally with 240 mL of water. Site personnel confirmed that the capsule had been taken by the study subject. In Cohort 1 (Part A), dosing of the first 2 subjects (1 active and 1 placebo) commenced at least 24 hours prior to the remaining 6 subjects. Dosing of the remaining subjects in the cohort proceeded if no safety issues were identified for the first 2 subjects.

For Part B of the protocol, subjects were dosed both at 8 AM ( $\pm 1$  hour) and approximately 12 hours later on Days 1-6, and once at 8 AM ( $\pm 1$  hour) on Day 7 for a total of 13 oral doses. Subjects were required to fast approximately 12 hours before prior to the first Day 1 dose.



Each cohort was dosed as follows:

<b>Cohort</b>	<b>Part A</b>
	<b>Treatment</b>
1 (n=8) <sup>a</sup>	LB-102 50 mg (n=6) or Matching Placebo (n=2) QD x 1 day
2 (n=8) <sup>b</sup>	LB-102 10 mg (n=6) or Matching Placebo (n=2) QD x 1 day
3 (n=8) <sup>b</sup>	LB-102 100 mg (n=6) or Matching Placebo (n=2) QD x 1 day
4 (n=8) <sup>b</sup>	LB-102 200 mg (n=6) or Matching Placebo (n=2) QD x 1 day
5 (n=8) <sup>b</sup>	LB-102 150 mg (n=6) or Matching Placebo (n=2) QD x 1 day
	<b>Part B</b>
6 (n=8)	LB-102 (n=6) 50 mg BID (100 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
7 (n=8)	LB-102 (n=6) 100 mg BID (200 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)
8 (n=8)	LB-102 (n=6) 75 mg BID (150 mg/day) x 6 days (Days 1-6) and QD x 1 day (Day 7) or Matching Placebo (n=2) BID x 6 days (Days 1-6) and QD x 1 day (Day 7)

<sup>a</sup> For Cohort 1, the first 2 subjects were randomized to receive LB-102 (n=1) or placebo (n=1) at least 24 hours prior to the remaining 6 subjects.

<sup>b</sup> For Cohorts 2-5, the doses were allowed to be reduced based on the pharmacokinetic results of Cohort 1. Cohort 2 was reduced from 100 mg to 10 mg. Cohort 3 was reduced from 200 mg to 100 mg. Cohort 4 was reduced from 400 mg to 200 mg. Cohort 5 was reduced from 800 mg to 150 mg.

QD = Once daily; BID = Twice daily

The doses do not increase in sequential order because the protocol allowed for dose adjustments. For example, dosage in Cohort 5 was reduced to 150 mg LB-102 QD after the Safety Review Committee recommended to lower the planned dose following QTcF prolongation in Cohort 4 associated with 200 mg LB-102 QD. Dosage for Cohort 8 was reduced to 75 mg BID after the Safety Review Committee recommended to lower the dose after 2 dystonia AEs occurred related to 100 mg LB-102 BID in Cohort 7.

#### 9.4.2 Identity of Investigational Product(s)

LB Pharmaceuticals, Inc. provided an adequate supply of active pharmaceutical ingredient (API) for the research site. The Pharmacist at the site mixed the API into the capsules.

LB-102 capsules at each dose level had matching placebo capsules. All study personnel, sponsor personnel, and vendors were blinded. Only the unblinded pharmacist knew which study participants were randomized to LB-102 or placebo.

#### 9.4.3 Method of Assigning Subjects to Treatment Groups

Upon confirmation of eligibility, subjects were randomized to LB-102 or placebo.

**Part A:** In each cohort, eight (8) new participants were enrolled, randomized 3:1 (LB-102 capsule: placebo capsules, i.e., 6 receiving LB-102 capsules and 2 receiving placebo capsules). Five (5) cohorts were enrolled for a total of 40 subjects receiving a single dose.

**Part B:** In each cohort, eight (8) new participants were enrolled, randomized 3:1 (LB-102 capsule: placebo capsules, i.e., 6 receiving LB-102 capsules and 2 receiving placebo capsules). Three (3) cohorts were enrolled for a total of 24 subjects receiving multiple doses.

Study randomization was computer generated.

#### **9.4.4 Selection of Doses in the Study**

Comprehensive, Good Laboratory Practice (GLP)-compliant, 28-day, oral repeat-dose toxicity studies have been conducted on LB-102 in rats and dogs. For both species, LB-102 was administered using the intended clinical treatment regimen which included oral dosing twice per day approximately 12 hours apart. In rats, doses of 0, 20, 40 and 100 mg/kg/dose (0, 40, 80, and 200 mg/kg/day) and in dogs doses of 0, 0.75, 3 and 7.5 mg/kg/dose (0, 1.5, 6 and 15 mg/kg/day) were administered. For both species, a 1-month post-dose recovery period occurred following 28 days of treatment. LB-102-related effects in rats were associated with elevated levels of prolactin, which are presumed to occur with LB-102 based on its mechanism of action as a dopamine antagonist. These changes are unique to rodents, and have been observed with other dopamine antagonists, were noted at all doses, and included hypertrophied corpora lutea (CLs), decreased CLs, interstitial cell hyperplasia and increased number of atretic follicles in the ovaries, mammary gland lobuloalveolar hyperplasia, and vaginal mucification in females and mammary gland atrophy and prostatic inflammation in males. Tissue changes either completely resolved or showed a trend to resolution during the recovery period. Given the species-specific nature of the response, the no-observed-adverse-effect-level (NOAEL) was determined to be 200 mg/kg/day, the highest dose administered. In dogs, the main finding was an increase in heart rate at 6 and 15 mg/kg/day. The dogs remained in sinus rhythm and, due to the lack of correlating clinical/veterinary observations, clinical pathology findings, or histopathological findings, this change was not considered to be adverse. Furthermore, no cardiovascular alterations were noted after the recovery period. The NOAEL was determined to be 15 mg/kg/day, the highest dose administered.

To determine, the initial starting dose in humans, the NOAEL doses in both species were converted to human equivalent doses (HED) using the FDA's (2005) guideline entitled "Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers." These corresponded to 32 and 8.1 mg/kg/day in rats and dogs, respectively. Dogs are the most sensitive species, therefore, applying a safety factor of 10, the initial starting dose in humans was 0.8 mg/kg/day (approximately equivalent to 50 mg/day for a 60 kg adult).

#### **9.4.5 Selection and Timing of Dose for Each Subject**

For Part A of the protocol, subjects were dispensed either a LB-102 capsule or matching placebo based on their assigned treatment at 8 AM ( $\pm 1$  hour) after fasting for approximately 12 hours. Subjects took the capsule orally with 240 mL of water.

For Part B of the protocol, subjects were dosed both at 8 AM ( $\pm 1$  hour) and approximately 12 hours later on Days 1-6, and once at 8 AM ( $\pm 1$  hour) on Day 7 for a total of 13 oral doses. Subjects were required to fast approximately 12 hours prior to the first Day 1 dose.

#### **9.4.6 Blinding**

This study was conducted under double-blind conditions so that neither the subject nor the Investigator or study staff members knew the identity of each subject's treatment. LB-102 was dispensed by an unblinded pharmacist to study staff for administration to the subjects. The blind was not broken during this study.

If the blind had been broken, according to the protocol, treatment assignment for an individual subject would have been unblinded only in an emergency, when knowledge of the treatment assignment was urgently needed for the clinical management or welfare of the subject. The Investigator would have contacted the Medical Monitor or project manager before unblinding, when possible, but priority would have been given to treatment of the subject. If unblinding would have occurred without prior approval, the Investigator would have promptly communicated the circumstances leading to the unblinding by telephone and in writing to the Medical Monitor.

Breaking of the blind, other than as described above, was considered a protocol violation. The blind was not broken during this study, but if it had been, any subject whose study drug treatment was unblinded would have been discontinued and the date, time, and reason for the unblinding would have been documented.

#### **9.4.7 Prior and Concomitant Therapy**

Prescription and over-the-counter medications were prohibited throughout the study except hormonal contraception for females of childbearing potential. No concomitant drug therapy was allowed during the study except one(s) required for the medical management of an AE. Any concomitant medication use was evaluated on a case-by-case basis by the Investigator or a Subinvestigator. Any concomitant medication used was recorded in the source document and on the appropriate CRF. The medication name, dose, frequency, date, and indication for use was recorded on the CRF. All concomitant medication use was documented from screening through study exit/early termination.

##### **9.4.7.1 Smoking**

Smoking was not allowed during the study.

##### **9.4.7.2 Dietary and Lifestyle Restrictions**

Subjects were required to refrain from the following dietary and/or lifestyle activities:

- Use of alcohol from 48 hours prior to Check-In through the end of the study.
- Use of any product containing caffeine or xanthine from 48 hours prior to Check-In through the end of the study.
- Any foods or beverages containing grapefruit or its juice, Seville oranges or star fruit from 48 hours prior to Check-In through the end of the study.
- Strenuous exercise 48 hours prior to Check-In through the end of the study.

### 9.4.8 Treatment Compliance

Study drug was administered at the investigational site by site staff. A mouth check was performed by investigational site staff to ensure study drug compliance. Dosing compliance was recorded by the Investigator or designee at the investigational site. The date and time of study drug administration was recorded.

## 9.5 Pharmacokinetics and Safety Variables

### 9.5.1 Pharmacokinetics and Safety Measurements Assessed and Flow Chart

For Part A, PK parameters of LB-102 and amisulpride include  $AUC_{0-t}$ ,  $AUC_{0-24}$ ,  $AUC_{0-inf}$ ,  $AUC\%/extrap$ ,  $CL/F$ ,  $C_{max}$ ,  $T_{max}$ ,  $\lambda_z$ , and  $t_{1/2}$ . For Part B (SAD), the PK parameters of LB-102 and amisulpride include  $AUC_{0-12, D1}$ ,  $AUC_{0-24, D1}$ ,  $AUC_{0-inf, D1}$ ,  $AUC\%/extrap, D1$ ,  $C_{max, D1}$ ,  $T_{max, D1}$ ,  $\lambda_z, D1$ , and  $t_{1/2, D1}$ ,  $AUC_{0-12, D7}$ ,  $AUC_{0-inf, D7}$ ,  $AUC_{extrap, D7}$ ,  $C_{max, D7}$ ,  $T_{max, D7}$ ,  $\lambda_z, D7$ ,  $t_{1/2, D7}$ , the accumulation ratio based on  $C_{max}$  after the first dose and last dose ( $R_{C_{max}}$ ), accumulation ratio based on AUC after the first and last dose ( $R_{AUC}$ ), linearity index (LI), apparent clearance at steady state ( $CL_{ss}/F$ ), and dosing interval ( $\tau$ ).

These PK parameters are summarized by cohort using descriptive statistics, including sample size, arithmetic means, geometric means, standard deviation, % coefficient of variation, minimum, median, and maximum.

For each subject in Part A, up to 16 and 18 blood samples were collected during the study for PK analysis for Cohorts 1-4 and Cohort 5, respectively. For each subject in Part B, up to 34 and 36 blood samples were collected during the study for PK analysis for Cohorts 6-7 and 8, respectively. The PK samples were obtained at the following time points:

- Part A
  - Day 1: pre-dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  minutes) post-dose.
  - Days 2-3: 24, 32, and 48 hours ( $\pm 15$  minutes) post Day 1 dose.
  - Days 8 and 15 (For Cohort 5, Part A only).
- Part B
  - For Cohorts 6-7:
    - Day 1: prior to the first dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  minutes) post-dose.
    - Days 2-6: prior to first dose.
    - Day 7: pre-dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  minutes) post-dose.
    - Days 8-9: 24, 32, and 48 hours ( $\pm 15$  minutes) post Day 7 dose.

- For Cohort 8 only:
  - Day 1: prior to the first dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1, 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  min) post first dose.
  - Days 2-5: prior to first dose.
  - Day 6: pre-dose, 15 and 30 minutes ( $\pm 5$  minutes), and 1, 2, 4, 8, 12, 12.25, 12.5, 13, 14, 16, 18, and 20 hours ( $\pm 15$  min) post dose.
  - Day 7: prior to first dose.
  - Days 8-9: 24, 32, and 48 hours ( $\pm 15$  min) post Day 7 dose.

Safety was assessed during the study by the monitoring and recording of AEs, clinical laboratory test results (hematology, biochemistry, and urinalysis), vital sign measurements (systolic and diastolic blood pressures, heart rate measured as pulse, respiratory rate, and temperature), ECG, and physical examination findings. Flow charts with the schedule of assessments are in [Table 2](#) (Part A) and [Table 3](#) (Part B).

### 9.5.2 Appropriateness of Measurements

All of the PK and safety assessments are standard and generally recognized as reliable, accurate, and relevant measurements.

### 9.5.3 Primary Efficacy Variable(s)

No efficacy analyses were performed for this study.

### 9.5.4 Drug Concentration Measurements

The plasma concentrations of LB-102 and amisulpride were obtained for PK parameters including  $AUC_{0-t}$ ,  $AUC_{0-24}$ ,  $AUC_{0-inf}$ ,  $AUC\%/extrap$ ,  $CL/F$ ,  $C_{max}$ ,  $T_{max}$ ,  $\lambda_z$ , and  $t_{1/2}$ .

## 9.6 Data Quality Assurance

To ensure data quality, this study used a GCP Monitoring Plan prepared by the Medpace Lead Clinical Research Associate to assure that the study was conducted according to international ethical and scientific quality standards.

Original source data was transcribed into the Target e\*CRF<sup>®</sup>, a validated 21 CFR Part 11 compliant Internet-based Electronic Data Capture (EDC) system, by the study Investigator or designated staff. The Investigator and staff were trained on the system prior to enrolment of the first subject. The Investigator reviewed and signed electronically the completed online eCRF at the end of the study.

A Data Management Plan (DMP) was created and managed by Target Health to provide data validation using Target e\*CRF<sup>®</sup>. Online edit checks, batch edit checks, and query management were performed. The study site addressed any queries, and an audit trail was created to document any changes to the database.

LB Pharmaceuticals, Inc. conducts clinical trials according to procedures that incorporate the ethical principles of GCP. To ensure compliance with these procedures and to assess the adequacy of quality control procedures, Target Health undertakes a GCP audit program.

Audits are performed by a quality assurance auditor that operates independently of the trial monitors. The audits within a clinical program are aimed at trial documentation, investigator sites and clinical trial reports.

The audit program, together with its internal quality control procedures, provides reassurance that trial conclusions are based on valid procedures for data management (DM) and analysis, and that the clinical trial program is carried out in accordance with GCP guidelines.

The investigator made all trial-related source data and records available at any time to a quality assurance auditor mandated by the Sponsor or to domestic/foreign regulatory inspectors or representatives from IRBs, who audited/inspected the trial.

## **9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size**

### **9.7.1 Statistical and Analytical Plans**

The Statistical Analysis Plan (SAP) is provided in [Appendix 16.1.9](#).

Descriptive statistics, namely sample size (n), mean, standard deviation, median, minimum and maximum for continuous variables, and count and percentage for categorical variables, are provided. No inferential statistics was performed, and no subgroup analysis was performed. Each cohort was evaluated separately for safety. All placebo subjects from the different cohorts were combined into a single group for summary purposes.

No imputation was made for missing values of safety endpoints except some missing data associated with AEs.

The last measurement obtained prior to the first dose of study treatment was used as baseline, which was the data collected during screening, check-in visit, or the pre-dose results on Day 1 visit, if applicable.

Safety data, including vital signs, ECGs, laboratory test results, physical examinations, and AEs were summarized by dose and assessment time points, as appropriate. Change from baseline was included in the summary tables for laboratory, ECG, and vital sign parameters.

PK parameters of LB-102 and amisulpride are summarized by cohort using descriptive statistics. Figures were created to display mean and individual subject LB-102 and amisulpride concentration time curves in plasma on both a linear and logarithmic scale. Dose proportionality was assessed using a linear regression, or other acceptable approach.

### **9.7.2 Determination of Sample Size**

The sample size for the study was based on clinical rather than statistical rationale. No formal sample size calculations were made. Cohorts of 8 subjects (6 active, 2 placebo) were sufficient to characterize the safety, tolerability, and PK profile of LB-102.

## 9.8 Changes in the Conduct of the Study or Planned Analyses

There were 5 protocol amendments over the course of this study. All 6 protocol versions are provided in [Appendix 16.1.1](#). The major changes for each amendment are listed below.

### [Amendment 1, 17 December 2019:](#)

- Study Design:
  - PK of LB-102 was added as an objective. Language was added stating that dosing of the first 2 subjects in Cohort 1 (Part A) will commence at least 24 hours prior to the remaining 6 subjects. Dosing for Cohorts 6-8 (Part B) was changed from BID for 7 days to BID for 6 days and QD on Day 7.
  - Day 3 for Part A of the protocol was added as an endpoint for C-SSRS.
  - Serum HbA1c was added to the screening visit for serum chemistry tests.
  - C-SSRS (MAD only) was added as a procedure at the Early Termination Visit.
  - If two or more subjects experience QTcF has been added to the list of stopping criteria. A new section was added to detail the QTcF criteria.
- Inclusion Criteria and Exclusion Criteria:
  - Females of child-bearing potential must have a negative pregnancy test was added to the Inclusion Criteria.
  - Additional exclusion criteria were added for fasting blood glucose, history of QT prolongation or dysrhythmia or a family history of prolonged QT interval or sudden death, and abnormal ECG findings.
- Reporting Pregnancies: This new section has been added.
- Subject Disposition and Demographic Characteristics: BMI was been added.
- Appendix 1 Clinical Pharmacology Summary Table: This section was added.

### [Amendment 2, 06 February 2020:](#)

- Safety Endpoints:
  - Blinded PK analysis will occur at the end of the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> cohorts for the SAD study instead of at the end of the 1<sup>st</sup> and 3<sup>rd</sup> cohorts.
  - Prolactin was added as a safety measurement on Day 8 of Part A and Day 15 of Part B. The values from Visit 1 will serve as a baseline for assessing potential post dose changes.

- Study Design for Part A:
  - Additional details regarding PK and dosing were added. The doses for cohorts 2-5 may be reduced based on the PK results of Cohort 1.
  - The dosing of the 3<sup>rd</sup> cohort will resume at 100 mg unless there is a clinical concern with safety in Cohort 2 and that dose escalation is designed to at least capture the exposure range. Dose escalation to 200 mg in Cohort 4 and 400 mg in Cohort 5 will be dependent on clinical observations.
  - The doses changed from the lowest 50 mg to the highest 800 mg to the lowest as 10 mg and the highest 400 mg.
- Laboratory Safety Assessments: A paragraph has been added saying that prolactin data will be de-identified prior to Investigator review during the Treatment period and de-identified prior to review by the SRC members. Subject IDs will be disclosed for clinical evaluation for prolactin levels that are  $\geq 100$  ng/mL.
- Appendix 1 Clinical Pharmacology Summary Table was updated to include PD Features for Part A 50 mg LB-102. Three (3) mild, Grade 1 AEs of elevated prolactin,  $\geq 100$  ng/mL, were reported as asymptomatic and considered definitely related to LB-102 in Cohort 1. All 3 AEs resolved by Day 8 on the Follow-up visit.

[Amendment 3, 08 April 2020:](#)

- The Investigator changed from Lukasz Biernat to Leela Vrishabhendra.
- Study Design:
  - For Cohort 5 (Part A), subjects will return for an additional Follow-up Visit (Day 15). The schedule of events for Part A have been updated.
  - Prolactin was added to be measured on Day 15 (for Cohort 5, Part A only).
  - ECG will be measured once at each time point for Cohorts 1-4 and in triplicate for Cohort 5. For Part B, ECG will be measured in triplicate at each time point.
  - PK samples have been added to Days 8 and 15 (for Cohort 5, Part A only).
  - Mean QTcF values will be used for Stopping Criteria.
  - 12-lead ECG will also be measured at 1, 3, 5, and 8 hours post-dose.
  - A physical exam will be done prior to the first dose on Day 2 for Visit 3.
  - It has been clarified that the neurological physical examination will focus on monitoring for manifestations of Extrapyrimalidal Symptoms.



- For Cohort 5, Part A, physical exam, weight measurements, vital signs, blood and urine samples for hematology, clinical chemistry, urinalysis, and urine pregnancy tests will be tested on Day 8 only. Plasma sample for PK analysis, blood and urine samples for prolactin, record concomitant medication use, and assess and record AEs will be completed on Days 8 and 15.
- Appendix 1 Clinical Pharmacology Summary Table was updated to include the PK Features as well as the PD Features for Cohorts 2-4. One (1) mild, Grade 1 AE of elevated prolactin  $\geq 100$  ng/mL was reported for both Cohorts 2 (10 mg) and 3 (100mg). In Cohort 4, there was one (1) mild, Grade 1 AE of QTcF prolongation and one (1) moderate, Grade 2 AE of acute dystonic reaction.

[Amendment 4, 18 May 2020:](#)

- Study Design:
  - Blinded PK analysis was changed to occur at the end of each Cohort (Cohorts 1-5) instead of at the end of the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> cohorts.
  - Prolactin was added as a safety measurement on Day 4 for Part B of the protocol.
  - LB-102 was clarified to be in dosage strengths of 25 mg, 50 mg, 75 mg, and 100 mg. However, this amendment language was an error and it should be clarified as in dosage strengths of 10 mg, 50 mg, 75 mg, and 100 mg.
  - In Part A, the treatment doses of LB-102 were reduced from 50 mg, 100 mg, 200 mg, 400 mg, and 800 mg to 50 mg, 10 mg, 100 mg, 200 mg, and 150 mg.
  - In Part B, the treatment doses of LB-102 were changed from Y\* mg, 2Y\* mg, and 3Y\* mg to 50 mg, Y\* mg, and Y\* mg. A standard physical examination was added on Day 2 in Part B of the protocol.
- Clinical Pharmacology Table was updated to include PK Features and PD Features of 150 mg of LB-102. PD Features for 200 mg dose in Cohort 4 was changed, indicating one (1) mild, Grade 1 AE of QTcF prolongation of  $>450$  msec and that one (1) moderate, Grade 2 AE resolved with no recurrence and that the subject was treated with concomitant medication for the symptoms.

[Amendment 5, 24 June 2020](#)

- Study Design:
  - Blinded PK analysis was changed to occur after each Cohort (Cohorts 6-8) for the MAD study.
  - In Part B, plasma PK samples for Cohort 8 only will be obtained at:
    - Day 1: prior to the first dose, 15, 30, and 45 minutes ( $\pm 5$  minutes), and 1,

- 1.5, 2, 3, 4, 6, 8, 12, and 16 hours ( $\pm 15$  min) post first dose.
- Days 2-5: prior to first dose.
- Day 6: pre-dose, 15 and 30 minutes ( $\pm 5$  minutes), and 1, 2, 4, 8, 12, 12.25, 12.5, 13, 14, 16, 18, and 20 hours ( $\pm 15$  min) post dose.
- Day 7: prior to first dose.
- In Part B, the treatment doses of LB-102 for Cohort 7 were changed from Y\* mg BID to 100 mg BID (200 mg/day) and for Cohort 8 were changed from Y\* mg BID to 75 mg BID (150 mg/day).
- Blood Collection was changed for each subject in Part B to up to 34 and 36 blood samples will be collected during the study for PK analysis for Cohorts 6-7 and 8, respectively.
- Appendix 1 Clinical Pharmacology Summary Table:
  - Updated to include Planned Dose Levels for Part B: 3 dose levels (BID), 50 mg (100 mg/day), 75 mg (150 mg/day), and 100 mg (200 mg/day). The principal AE of Acute Dystonic Reaction was added.
  - PK Features were updated for Part B to include Mean  $T_{max}$  [50 mg BID (Day 1: 2.250 h, Day 7: 2.333 h) and 100 mg BID (Day 1: 2.25 h, Day 7: Not enough data)], Mean Terminal  $t_{1/2}$  [50 mg BID (Day 1: 4.962 h, Day 7: 4.088 h) and 100 mg BID (Day 1: 4.331 h, Day 7: Not enough data)], Mean CL/F or CL [50 mg BID (Day 1: N/A, Day 7: 33.778 L/h) and 100 mg BID (Day 1: N/A, Day 7: Not enough data)].
  - PD Features were added for Cohort 6 and 7. In Cohort 6 there were 2 mild, Grade 1 AEs (elevated prolactin,  $> 100$  ng/mL) by 2 subjects on Day 9 (Both subjects were asymptomatic). The AEs were considered definitely related to LB-102 and resolved by Day 15 Follow-Up Visit. In Cohort 7 there was 1 mild, Grade 1 AE (elevated prolactin,  $> 100$  ng/mL) experienced by 1 subject on Day 3 (subject was asymptomatic). The AE was considered definitely related to LB-102 and resolved by Day 11 Follow-Up Visit. Two (2) moderate, Grade 2 AEs (acute dystonic reaction) were experienced by 2 subjects on Day 3, 1- and 3-hours post dose, respectively. The acute dystonic reaction was definitely related to the study drug in Cohort 7. Both AEs resolved on the same day following treatment with concomitant medication for the symptoms. No recurrences were experienced by both subjects. According to [Section 8.5.3](#) of the LB-102-001 Clinical Protocol (Version 5, 18 May 2020), this triggered a stopping criterion (two or more LB-102 or placebo- treated subjects experience a  $\geq$  Grade 2 AE in the same system organ class that is not clearly unrelated to LB-102 or placebo) for Cohort 7. The Investigator and Sponsor agreed to immediately halt dosing for all subjects in Cohort 7 for the safety of the remaining subjects on 04 June 2020. In accordance with Section 8.5.3 of the Clinical Protocol, and based on the discussion of the PK and Safety Tolerability of the 100 mg (BID; 200 mg/day) dose of LB-102 (Cohort 7), the SRC voted for an

intermediate dose of 75 mg BID (150 mg/day; lower than the Cohort 7 dose of 100 mg BID [200 mg/day]) for Cohort 8 (LB-102-001 Cohort 7 SRC Meeting Minutes, 22Jun2020).

## 10. STUDY SUBJECTS

### 10.1 Disposition of Subjects

There were 288 subjects screened for the study. A total of 64 subjects enrolled and 224 failed screening. Six subjects were randomized in each cohort (1-8) to receive LB-102 and 16 subjects (2 in each cohort) were randomized to placebo as described in [Table 4](#). All subjects in Cohorts 1-6 completed the study. All 6 subjects in Cohort 7, 1 subject in Cohort 8, and 2 subjects in placebo did not complete the study due to either subject withdrawal or other reasons.

One (1) subject taking 100 mg LB-102 BID (Cohort 7, 01S2069) withdrew from the study for personal/family reasons after receiving their last dose on Day 2 in the morning. This subject had a Grade 1 AE of elevated prolactin on Day 3 and was asymptomatic at all time points. Two (2) additional subjects taking 100 mg LB-102 BID (Cohort 7, 01S2066 and 01S2079) experienced a Grade 2 AE (Acute Dystonic Reaction) starting 1 hour and 3 hours post-first dose, respectively, on Day 3. The subjects withdrew consent prior to the AE for personal/family or work issues. According to [Section 8.5.3](#) of the LB-102-001 Clinical Protocol (Version 5, 18 May 2020), two AEs in the same system organ class that is not clearly unrelated to LB-102 or placebo, met a stopping criterion. Dosing was then halted for all subjects in Cohort 7, including the 2 placebo subjects.

In subjects taking 75 mg LB-102 BID (Cohort 8), 1 subject (01S2092) similarly experienced an acute dystonic reaction on Day 3 after the first dose. Study drug administration was halted in response to this AE and the subject withdrew consent the following day.

**Table 4: Disposition of Subjects Randomized**

		Treatment Group								
		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1 (50 mg QD)	Cohort 2 (10 mg QD)	Cohort 3 (100 mg QD)	Cohort 4 (200 mg QD)	Cohort 5 (150 mg QD)	Cohort 6 (50 mg BID)	Cohort 7 (100 mg BID)	Cohort 8 (75 mg BID)	
Randomized	N	6	6	6	6	6	6	6	6	16
Treated	N	6	6	6	6	6	6	6	6	16
Completed the Study	Yes	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	0 (0.0%)	5 (83.3%)	14 (87.5%)
	No	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (100.0%)	1 (16.7%)	2 (12.5%)
Primary Reason for Discontinuation	AE	0	0	0	0	0	0	0	0	0
	Protocol Deviation	0	0	0	0	0	0	0	0	0
	Withdrawal by Subject	0	0	0	0	0	0	3 (50%)	1 (16.7%)	0
	Lost to Follow-up	0	0	0	0	0	0	0	0	0
	Investigator Recommendation	0	0	0	0	0	0	0	0	0
	Other	0	0	0	0	0	0	3 (50%)	0	2 (12.5%)

Ref: [Statistical Table 14.1.1.](#)

## 10.2 Protocol Deviations

According to the [Protocol Deviation Plan](#) (Version 22 May 2020), a clinical study report (CSR) reportable protocol deviation were either, 1. A subject that did not meet entry criteria, 2. A subject that developed withdrawal criteria but were not withdrawn, 3. A subject that received the wrong treatment or incorrect dose, or 4. A subject that received an excluded medication. Some of the key CSR non-reportable protocol deviations included, 1. Study procedure or vital signs were not conducted at study visit, or was out of window, 2. Subject was not resting in the correct position for the required time frame prior to ECG measurement, 3. 12-lead safety ECG was not performed within scheduled time window, 4. PK sample not collected or drawn outside of allowable time window, and 5. Subject was not fasting for a minimum of 8 hours prior to serum chemistry laboratory testing.

There were no major protocol deviations reported in this study, and all deviations (30) were considered non-CSR reportable. [Data Listing 16.2.2](#) contains details for each minor deviation. Minor deviations included study visit was completed out of window (3), subjects not fasting for a minimum of 8 hours prior to serum chemistry laboratory testing (5), a missing PK blood sample (1), vital signs not conducted according to protocol (8), subjects not resting in supine or seated positions for the required amount of time prior to performing vital signs (10), ECG not performed in triplicate (1), and ECG not recorded within  $\pm 30$  seconds from scheduled time point (2). Additionally, minor deviations between the actual and the scheduled time of PK blood sampling occurred and are found in the individual listings provided in the [PK Report](#) (Appendix 16.1.9).

## 11. EFFICACY EVALUATION

### 11.1 Data Sets Analyzed

Sixty-four healthy subjects (40 in Part A and 24 in Part B) were enrolled to participate in this clinical trial. The PK Population (N= 48) included all of the subjects who were randomized, had received at least one dose of LB-102, and had at least one post-dose measureable concentration of LB-102. The metabolite, amisulpride, was also elevated in all subjects but was only detected in subjects receiving at least 50 mg QD. No subjects were excluded from PK analysis. Individual subject data listings are provided in [Data Listings 16.2.1](#) through [16.2.8.5](#).

### 11.2 Demographics and Other Baseline Characteristics

#### 11.2.1 Demographics

Age, gender, race, height, weight, and body mass index (BMI) for cohorts 1-8 and the placebo group are listed in [Table 5](#) and [Statistical Table 14.1.2](#).

The demographics of the individual subjects are provided in [Data Listing 16.2.4.1](#).

**Table 5: Demographics and Baseline Characteristics**

		Treatment Group								
		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1 (50 mg QD)	Cohort 2 (10 mg QD)	Cohort 3 (100 mg QD)	Cohort 4 (200 mg QD)	Cohort 5 (150 mg QD)	Cohort 6 (50 mg BID)	Cohort 7 (100 mg BID)	Cohort 8 (75 mg BID)	
N		6	6	6	6	6	6	6	6	16
Age (years)	Mean	37.2	31.3	35.0	28.8	31.0	31.7	34.8	44.0	40.1
	SD	8.2	10.7	9.8	11.7	11.5	4.9	9.8	8.7	12.3
	Median	38.5	27.5	31.5	25.5	29.0	32.5	35.5	44.5	43.0
	Range	22-45	21-47	26-54	18-45	19-44	23-37	21-48	32-53	20-55
Sex	Male	2 (33.3%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	6 (100.0%)	5 (83.3%)	4 (66.7%)	12 (75.0%)
	Female	4 (66.7%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	0 (0.0%)	1 (16.7%)	2 (33.3%)	4 (25.0%)
Race	American Indian or Alaska Native	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Asian	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Black or African American	2 (33.3%)	3 (50.0%)	4 (66.7%)	6 (100.0%)	5 (83.3%)	4 (66.7%)	5 (83.3%)	2 (33.3%)	9 (56.3%)
	Native Hawaiian or other Pacific Islander	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	White	3 (50.0%)	3 (50.0%)	2 (33.3%)	0 (0.0%)	1 (16.7%)	2 (33.3%)	1 (16.7%)	4 (66.7%)	7 (43.8%)
	Multiple	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Height (cm)	Mean	166.8	168.5	183.0	171.7	174.9	174.5	175.2	170.6	172.6
	SD	7.5	8.8	10.0	7.3	6.6	3.3	7.8	11.0	9.5
	Range	159-180	157-178	168-191	164-182	163-182	169-178	168-190	157-182	154-187
Weight (kg)	Mean	72.1	68.7	85.0	71.2	74.5	79.4	69.9	70.1	75.3
	SD	13.5	15.7	18.0	6.4	7.8	8.6	6.8	8.4	11.2
	Range	57-97	51-87	61-107	64-81	63-85	66-91	60-79	59-82	52-93
BMI (kg/m <sup>2</sup> )	Mean	25.7	23.9	25.3	24.2	24.3	26.0	22.8	24.1	25.1
	SD	3.2	3.1	4.2	3.3	2.1	2.5	3.1	2.0	2.4
	Range	20-30	21-28	21-30	20-28	21-27	23-30	19-27	22-28	22-30

Ref: [Statistical Table 14.1.2](#).

### 11.2.2 Medical History

Medical history data for each cohort are found in [Statistical Table 14.1.3](#). Medical histories for individual subjects are provided in [Data Listing 16.2.4.3](#). Below is a summary of the medical history for the 64 subjects randomized.

For blood and lymphatic system disorders, two subjects had a medical history of anemia (01S0116, Cohort 4, 200 mg QD; 01S0075, Placebo).

For congenital, familial and genetic disorders, 1 subject had a history of hydrocele (01S0074, Cohort 3, 100 mg QD) and 1 subject had pulmonary malformation (01S0008 Cohort 1, 50 mg QD).

For eye disorders, 11 subjects had myopia (Cohort 3, 100 QD, N=3; Cohort 5, 150 mg QD, N=1; Cohort 6, 50 mg BID, N=2; Cohort 8, 75 mg BID, N=1; Placebo, N=3).

Of the subjects with gastrointestinal disorders, 3 had a history of inguinal hernia (01S0168, Cohort 5, 150 mg QD; 01S2093, Cohort 8, 75 mg BID; 01S0001, Placebo), 21 subjects had a history of tooth impacted, and 1 subject had an umbilical hernia (01S0109, Cohort 4, 200 mg QD).

For immune system disorders, 1 subject had allergy to animal (01S0074, Cohort 3, 100 mg QD), 2 subjects had food allergy (01S0063, Cohort 3, 100 mg QD and 01S2045, Cohort 6, 50 mg BID), and 5 subjects had seasonal allergy (Cohort 3, 100 mg QD, N=1; Cohort 4, 200 mg QD, N=1; Cohort 5, 150 mg QD, N=1; Cohort 7, 100 mg BID, N=2).

Four (4) subjects had a history of infections and infestations including 3 subjects with appendicitis (01S2059 and 01S2079, Cohort 7, 100 mg BID and 01S0068, Placebo) and 1 subject with tonsillitis (01S2042, Placebo).

A total of 11 subjects had a history of injury, poisoning and procedural complications including ankle fracture (01S0099, Placebo), clavical fracture (01S2053, Cohort 6, 50 mg BID), femur fracture (01S0042, Cohort 2, 10 mg QD), gun shot wound (01S2079, Cohort 7, 100 mg BID), ligament injury (01S0104, Cohort 4, 200 mg QD), ligament rupture (01S0003, Cohort 1, 50 mg QD; 01S2050, Cohort 6, 50 mg BID; 01S2078, Cohort 7, 100 mg BID; 01S2042, Placebo), superficial injury of eye (01S0104, Cohort 4, 200 mg QD), and wrist fracture (01S0162, Cohort 5, 150 mg QD).

For investigations, 1 subject had a history of cardiac murmur (01S0071, Cohort 3, 100 mg QD) and 1 subject had a laparoscopy (01S2065, Placebo).

For musculoskeletal and connective tissue disorders, 1 subject had back pain (01S0071, Cohort 3, 100 mg QD), 1 had rotator cuff syndrome (01S0037, Placebo), 1 had scoliosis (01S2034, Cohort 6, 50 mg BID), 1 had a synovial cyst (01S0075, Placebo), and 1 had a tibia fracture (01S2055, Cohort 6, 50 mg BID).

For neoplasms benign, malignant and unspecified including cysts and polyps, 1 subject had a history of uterine leiomyoma (01S0157, Cohort 5, 150 mg QD).

For nervous system disorders, two subjects had a history of headache (01S0063, Cohort 3, 100 mg QD; 01S2042, Placebo).

For pregnancy, puerperium and perinatal conditions, 1 subject had a spontaneous abortion (01S2065, Placebo).

For renal and urinary disorders, 1 subject had a history of nephrolithiasis (01S2042, Placebo).

For reproductive system and breast disorders, 3 subjects had dysmenorrhea (01S0063, Cohort 3, 100 mg QD; 01S2065 and 01S0075, Placebo), 1 subject had testicular torsion (01S2092, Cohort 8, 75 mg BID), and 1 subject had uterine prolapse (01S0037, Placebo).

For respiratory, thoracic and mediastinal disorders, 1 subject had a history of adenoidal disorder (01S0010, Cohort 1, 50 mg QD) and 1 subject had exercise induced asthma (01S2076, Cohort 7, 100 mg BED).

For skin and subcutaneous tissue disorders, 1 subject had eczema (01S0165, Cohort 5, 150 mg QD) and two subjects had urticaria (01S0063, Cohort 3, 100 mg QD; 01S0160, Cohort 5, 150 mg QD).

### 11.2.3 Concomitant Medications

Concomitant medications for each subject can be found in [Data Listing 16.2.4.2](#).

Throughout the study, 3 subjects were taking oral contraceptives (progestogens and/or estrogens). Subject 01S0003 (Cohort 1, 50 mg QD) was taking etonogestrel, subject 01S0032 (Cohort 2, 10 mg QD) was taking a fixed combination of drospirenone and ethinylestradiol, and subject 01S0071 (Cohort 3, 100 mg QD) was taking a fixed combination of levonorgestrel and ethinylestradiol.

During the screening period, subjects 01S0120 (Cohort 4, 200 mg QD) and 01S2078 (Cohort 7, 100 mg BID) were taking multivitamins until February 16<sup>th</sup>, 2020 (Day -17) and May 19<sup>th</sup>, 2020 (Day -15), respectively. Subject 01S2042 (Placebo) took paracetamol (analgesics) on April 12<sup>th</sup>, 2020 (Day -30). Note these were recorded as concomitant medications to confirm washout of at least 14 days prior to the start of treatment.

### 11.2.4 Physical Examination

Physical examination results for the subject cohorts are summarized and provided in [Statistical Table 14.3.5.3.1](#). Individual physical examinations are listed in [Data Listing 16.2.8.5](#).

A total of 13 subjects (Cohort 1, 50 mg QD, N=2; Cohort 2, 10 mg QD, N=1; Cohort 4, 200 mg QD, N=1; Cohort 6, 50 mg BID, N=3; Cohort 7, 100 mg BID, N=3; Cohort 8, 75 mg BID, N=1; Placebo, N=2) had an abnormal, but not clinically significant, skin examination at baseline. Two (2) subjects in the Placebo group had an abnormal, but not clinically significant, ear examination at baseline. All other physical examinations were listed as normal at baseline.



### 11.2.5 Laboratory Test Results

All subjects were negative for a urine drug screen ([Data Listing 16.2.6.1](#)) and alcohol breathalyzer test ([Data Listing 16.2.6.2](#)). All female subjects were not pregnant ([Data Listing 16.2.6.3](#)).

[Statistical Tables 14.3.4.1.1](#) to [14.3.4.1.11](#) contain summaries of the chemistry laboratory data. [Data Listing 16.2.8.1.1](#) contains individual listings for chemistry laboratory test results. There were few laboratory chemistry values slightly above or below the normal range at baseline ([Table 6](#)). There were no subjects with out of range alanine aminotransferase or aspartate aminotransferase concentrations. One (1) subject (01S0030, Cohort 2, 10 mg QD) had high prolactin at baseline (28.5 µg/L) and 1 subject (01S0028, Placebo) had low prolactin (4.7 µg/L). Two (2) subjects had low alkaline phosphatase with the lowest being 37 IU/L. Creatinine was high in 7 subjects, with the highest value being 1.37 mg/dL and was low (0.52 mg/dL) in 1 subject. HbA1C was low in 6 subjects with the lowest value being 4.6%. HbA1C was elevated in 3 subjects who all had a value of 5.7%. Two (2) subjects had low protein (5.9 g/dL and 5.3 g/dL). Albumin was low (3.5 g/dL) in 1 subject. Eight (8) subjects had elevated fasting glucose ( $\geq 100$  mg/dL), with the maximum concentration being 107 mg/dL. Bilirubin was high (1.6 mg/dL) in 1 subject and urea nitrogen was high (21 mg/dL) in 1 subject.

Summaries of hematology data for each cohort are located in [Statistical Tables 14.3.4.2.1](#) to [14.3.4.2.15](#). Individual listings for hematology test results are found in [Data Listing 16.2.8.1.2](#). At baseline, there were few out of range values ([Table 7](#)) Platelets were high in 2 subjects ( $464 \times 10^9/L$  and  $473 \times 10^9/L$ ), and low in 2 subjects ( $148 \times 10^9/L$  and  $144 \times 10^9/L$ ). Neutrophils were low in 4 subjects, with the lowest value being  $1.0 \times 10^9/L$ . Eosinophils were high in 3 subjects, with the highest being  $0.7 \times 10^9/L$ . Leukocytes were low in 2 subjects ( $2.9 \times 10^9/L$  and  $2.7 \times 10^9/L$ ). Erythrocytes were high in 1 subject ( $6.17 \times 10^{12}/L$ ). Hematocrit was low in 1 subject (36.9 %). Hemoglobin was low in 1 subject (12.6 g/dL).

Summaries of urinalysis test results for each cohort are located in [Statistical Tables 14.3.4.3.1](#) to [14.3.4.3.10](#). Individual listings for urinalysis test results are found in [Data Listing 16.2.8.1.3](#). At baseline, there were few out of range values ([Table 8](#)). Specific gravity was abnormally low ( $\leq 1.005$ ) in 9 subjects and high ( $\geq 1.030$ ) in 2 subjects. Urinary pH was abnormally high ( $\geq 9.0$ ) in 1 subject and high (8.0) in 1 subject. Glucose was high (+1) in 1 subject. Ketones were abnormal (trace) in 1 subject. Leukocyte Esterase was abnormal (trace) in 1 subject.

### 11.2.6 Vital Signs

Summaries of vital signs at the screening visit for each cohort are located in [Statistical Table 14.3.5.1](#). Individual listings for vital signs are found in [Data Listing 16.2.8.2](#). [Table 9](#) summarizes blood pressure, pulse rate, respiratory rate, and body temperature for each cohort at baseline (Day 1 pre-dose). Systolic blood pressure ranged between 101-148 mmHg. There was only 1 subject (01S0169, Placebo) who had systolic blood pressure  $\geq 135$  mmHg (148 mmHg). Diastolic blood pressure ranged between 61-93 mmHg and was elevated ( $\geq 90$  mmHg) in 5 subjects (Cohort 1, 50 mg QD, N=1; Cohort 5, 150 mg QD, N=1; Cohort 6, 50 mg BID, N=1; Cohort 8, 75 mg BID, N=1; Placebo, N=1). Pulse rate was generally within normal range (49-94 beats/min). Two (2) subjects in Cohort 7, 100 mg BID had a low resting pulse rate (50 beats/min and 53 beats/min) and 2 subjects in Placebo had low resting pulse rate (49 beats/min and 53 beats/min). Respiratory rate (range: 12-17 breaths/min) and body temperature (range: 36.3-37.5 °C) were generally normal for all subjects.

**Table 6: Number of Subjects with High and Low Chemistry Laboratory Values at Baseline**

		Treatment Group								
		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1 (50 mg QD)	Cohort 2 (10 mg QD)	Cohort 3 (100 mg QD)	Cohort 4 (200 mg QD)	Cohort 5 (150 mg QD)	Cohort 6 (50 mg BID)	Cohort 7 (100 mg BID)	Cohort 8 (75 mg BID)	
	N	6	6	6	6	6	6	6	6	16
Prolactin (µg/L)	High	0	1	0	0	0	0	0	0	0
	Low	0	0	0	0	0	0	0	0	1
Alkaline Phosphatase (IU/L)	High	0	0	0	0	0	0	0	0	0
	Low	0	0	0	0	0	0	1	0	1
Creatinine (mg/dL)	High	0	0	2	0	2	1	0	0	2
	Low	0	0	0	0	0	0	0	0	1
HbA1C (%)	High	1	1	0	0	0	1	0	0	0
	Low	1	1	1	0	0	1	1	0	1
Protein (g/dL)	High	0	0	0	0	0	0	0	0	0
	Low	0	0	0	0	0	1	0	0	1
Albumin (g/dL)	High	0	0	0	0	0	0	0	0	0
	Low	0	0	0	0	0	0	0	0	1
Glucose (mg/dL)	High	0	2	0	1	1	3	0	0	1
	Low	0	0	0	0	0	0	0	0	0
Bilirubin (mg/dL)	High	0	0	1	0	0	0	0	0	0
	Low	0	0	0	0	0	0	0	0	0
Urea Nitrogen (mg/dL)	High	0	0	0	0	0	0	0	0	1
	Low	0	0	0	0	0	0	0	0	0

Ref: [Data Listing 16.2.8.1.1](#).

**Table 7: Number of Subjects with High and Low Hematology Laboratory Values at Baseline**

		Treatment Group								
		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1 (50 mg QD)	Cohort 2 (10 mg QD)	Cohort 3 (100 mg QD)	Cohort 4 (200 mg QD)	Cohort 5 (150 mg QD)	Cohort 6 (50 mg BID)	Cohort 7 (100 mg BID)	Cohort 8 (75 mg BID)	
	N	6	6	6	6	6	6	6	6	16
Plateletes (10 <sup>9</sup> /L)	High	1	0	0	1	0	0	0	0	0
	Low	1	0	0	0	0	0	0	0	1
Neutrophils (10 <sup>9</sup> /L)	High	0	0	0	0	0	0	0	0	0
	Low	0	1	0	0	0	1	1	0	1
Eosinophils (10 <sup>9</sup> /L)	High	0	0	1	0	1	0	1	0	0
	Low	0	0	0	0	0	0	0	0	0
Leukocytes (10 <sup>9</sup> /L)	High	0	0	0	0	0	0	0	0	0
	Low	0	0	1	0	0	0	1	0	0
Erythrocytes (10 <sup>12</sup> /L)	High	0	0	0	1	0	0	0	0	0
	Low	0	0	0	0	0	0	0	0	0
Hematocrit (%)	High	0	0	0	0	0	0	0	0	0
	Low	0	0	0	0	0	0	0	0	1
Hemoglobin (g/dL)	High	0	0	0	0	0	0	0	0	0
	Low	0	0	0	0	0	0	0	0	1

Ref: [Data Listing 16.2.8.1.2.](#)

**Table 8: Number of Subjects with Abnormal Urinalysis Results at Baseline**

		Treatment Group								
		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1 (50 mg QD)	Cohort 2 (10 mg QD)	Cohort 3 (100 mg QD)	Cohort 4 (200 mg QD)	Cohort 5 (150 mg QD)	Cohort 6 (50 mg BID)	Cohort 7 (100 mg BID)	Cohort 8 (75 mg BID)	
	N	6	6	6	6	6	6	6	6	16
Specific Gravity	High	0	1	0	0	1	0	0	0	0
	Low	1	0	0	2	3	0	1	1	1
pH	High	0	0	1	0	0	0	0	1	0
Glucose	(+1)	0	0	0	1	0	0	0	0	0
Ketones	Trace	0	0	0	0	1	0	0	0	0
Leukocyte Esterase	Trace	0	0	0	0	0	0	0	0	0

Ref: [Data Listing 16.2.8.1.3](#).

**Table 9: Vital Signs on Day 1 Pre-Dose**

		Treatment Group								
		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1 (50 mg QD)	Cohort 2 (10 mg QD)	Cohort 3 (100 mg QD)	Cohort 4 (200 mg QD)	Cohort 5 (150 mg QD)	Cohort 6 (50 mg BID)	Cohort 7 (100 mg BID)	Cohort 8 (75 mg BID)	
N		6	6	6	6	6	6	6	6	16
Systolic Blood Pressure, mmHg	Mean	122.2	114.3	115.5	119.0	118.5	121.8	114.5	119.3	119.9
	SD	12.0	6.1	6.7	6.7	10.5	10.4	8.5	9.1	12.2
	Range	107-134	108-122	107-124	111-130	106-133	108-135	101-124	108-129	102-148
Diastolic Blood Pressure, mmHg	Mean	83.8	73.2	77.2	78.5	75.8	82.5	76.8	81.0	80.1
	SD	6.3	4.8	5.3	5.7	10.7	6.3	5.6	6.8	5.8
	Range	75-91	65-78	67-82	72-88	61-90	75-93	71-84	71-91	71-91
Pulse Rate, beats/min	Mean	76.5	74.0	73.0	73.7	67.5	66.3	61.3	68.0	69.1
	SD	14.1	15.9	7.9	12.3	6.3	5.3	15.4	5.1	12.3
	Range	65-99	55-97	60-83	60-93	59-75	57-71	50-92	61-76	49-94
Respiratory Rate, breaths/min	Mean	14.7	15.7	15.8	15.0	15.3	15.3	14.7	14.7	14.8
	SD	1.0	0.8	1.0	1.0	1.1	1.0	1.0	1.0	1.2
	Range	14-16	14-16	14-17	14-16	14-16	14-16	14-16	14-16	12-16
Temperature, °C	Mean	36.80	37.03	36.93	36.63	36.73	36.73	36.80	36.78	36.75
	SD	0.17	0.26	0.10	0.15	0.15	0.23	0.34	0.13	0.14
	Range	36.5-37.0	36.7-37.5	36.8-37.1	36.5-36.9	36.5-36.9	36.5-37.1	36.3-37.3	36.6-36.9	36.6-37.1

Ref: [Statistical Table 14.3.5.1.](#)

### 11.2.7 Electrocardiogram

Summaries of ECG results at baseline for each cohort are located in [Statistical Table 14.3.5.2](#) and [Table 10](#). Individual listings for ECG results are found in [Data Listing 16.2.8.3](#). On Day 1 at pre-dose, ECG was interpreted as abnormal in 2 subjects receiving 50 mg LB-102 QD (Cohort 1), 4 subjects receiving 10 mg LB-102 QD (Cohort 2), 3 subjects receiving 100 mg LB-102 QD (Cohort 3), 3 subjects receiving 200 mg LB-102 QD (Cohort 4), 4 subjects receiving 150 mg LB-102 QD (Cohort 5), 5 subjects receiving 50 mg LB-102 BID (Cohort 6), 3 subjects receiving 200 mg LB-102 QD (Cohort 7), 4 subjects receiving 75 mg LB-102 QD (Cohort 8), and 8 subjects receiving placebo.

Heart rate ranged between 41-80 beats/min and was low (<50 beats/min) in 4 subjects (01S0073, Cohort 3, 100 mg QD; 01S0162, Cohort 5, 150 mg QD; 01S0037, Placebo; 01S2042, Placebo). PR interval was normal in all subjects. QRS duration was slightly elevated (>100 msec) in 15 subjects with the longest duration being 117 msec. QT interval was elevated (>440 msec) in 2 subjects (481 msec, 01S0073, Cohort 3, 100 mg QD; 446 msec, 01S2042, Placebo). QTcF interval was generally normal and ranged between 362-431 msec. The subject with 431 msec QTcF interval was a 37-year-old male (01S0010, Cohort 1, 50 mg QD).

### 11.2.8 Columbia-Suicide Severity Rating Scale (C-SSRS)

The C-SSRS questionnaire results at the screening visit for each cohort are located in [Statistical Table 14.3.5.5](#). Individual listings for C-SSRS results are found in [Data Listing 16.2.8.4](#). No subjects reported yes to any question on the C-SSRS at the screening visit.

**Table 10: Electrocardiogram Results on Day 1 Pre-dose**

		Treatment Group								
		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1 (50 mg QD)	Cohort 2 (10 mg QD)	Cohort 3 (100 mg QD)	Cohort 4 (200 mg QD)	Cohort 5 (150 mg QD)	Cohort 6 (50 mg BID)	Cohort 7 (100 mg BID)	Cohort 8 (75 mg BID)	
N		6	6	6	6	6	6	6	6	16
Heart Rate, beats/min	Mean	64.8	61.7	59.5	59.5	61.1	61.6	56.4	59.3	62.0
	SD	8.0	10.5	10.7	10.2	10.1	6.0	9.4	7.0	9.0
	Range	56.0-79.0	52.0-80.0	41.0-70.0	51.0-79.0	43.7-71.0	51.3-67.7	51.0-75.0	52.0-68.7	47.0-75.0
PR Interval, Aggregate (msec)	Mean	145.7	167.0	168.5	141.5	163.7	172.4	155.7	171.3	165.6
	SD	14.0	19.5	14.8	14.2	9.3	20.7	15.7	17.7	20.1
	Range	123-160	140-189	153-191	121-158	151-177	142-195	136-181	148-191	133-193
QRS Duration, Aggregate (msec)	Mean	88.8	91.7	95.3	98.2	93.7	94.2	89.6	90.8	96.5
	SD	4.4	9.4	14.6	9.6	5.4	7.8	3.9	5.3	10.2
	Range	83-95	81-103	77-117	89-113	87-99	88-108	84-95	81-94	78-112
QT Interval, Aggregate (msec)	Mean	402.8	386.3	405.0	401.8	389.6	392.8	408.7	395.2	396.3
	SD	18.1	25.9	42.3	25.7	31.2	23.8	25.9	25.2	19.7
	Range	373-418	361-436	372-481	366-432	355-427	361-431	369-432	364-434	367-446
QTcF Interval, msec	Mean	412.5	388.0	400.4	399.0	389.3	395.6	398.5	392.4	399.2
	SD	17.7	17.0	17.0	20.3	17.6	22.1	12.4	16.2	16.4
	Range	381-431	366-416	374-424	363-419	375-414	362-418	379-410	376-420	369-417
R-R Interval, msec	Mean	936.4	994.6	1041.4	1029.3	1010.9	983.1	1083.8	1024.9	988.5
	SD	107.2	153.8	223.9	148.3	196.8	102.4	145.6	117.3	151.3
	Range	759-1071	750-1154	857-1463	759-1176	847-1375	887-1169	801-1178	876-1154	800-1277

Ref: [Statistical Table 14.3.5.2](#).

### 11.3 Measurements of Treatment Compliance

For Part A (SAD), Cohorts 1-5 took either 50 mg, 10 mg, 100 mg, 200 mg, or 150 mg of LB-102 once-daily (QD) on Day 1, respectively. For Part B (MAD), it was planned for Cohorts 6-8 to take either 50 mg, 100 mg, or 75 mg of LB-102 twice-daily (BID) on Days 1-6 and once-daily on Day 7, totaling 13 doses.

Treatment compliance was calculated as the number of subjects who completed all drug doses. There was 100% compliance for Cohorts 1-6, 0.0% for Cohort 7, 83.3% for Cohort 8, and 87.5% for Placebo ([Statistical Table 14.1.4](#)).

All subjects in Cohort 7 ended treatment early on either Day 2 (1 subject, 100 mg LB-102 BID) or Day 3 (5 subjects, 100 mg LB-102 BID; 2 subjects, Placebo). One (1) subject in Cohort 7 (01S2069) withdrew from the study after receiving their last dose on Day 2 in the morning. Two (2) subjects (01S2066 and 01S2079) in Cohort 7 experienced a Grade 2 AE (acute dystonic reaction), which met a stopping criterion and treatment was halted in the remaining 5 subjects (100 mg BID LB-102, N=3; Placebo, N=2). One (1) subject in Cohort 8 (01S2092) similarly experienced an acute dystonic reaction on Day 3 and treatment was halted. The subject voluntarily withdrew consent the next day. The listing for individual treatment compliance is found in [Data Listing 16.2.5](#).

### 11.4 Pharmacokinetic Results and Tabulations of Individual Patient Data

#### 11.4.1 Analysis of Pharmacokinetics

Plasma concentrations, PK parameters, and dose proportionality analysis of LB-102 and its metabolite, amisulpride, were analyzed in the [PK Report](#) provided in Appendix 16.1.9.

##### 11.4.1.1 Plasma Concentrations

###### 11.4.1.1.1 Part A (SAD) Plasma Concentration After a Single Oral Dose

Descriptive statistics and individual listings of plasma LB-102 and amisulpride concentrations after a single dose for the PK Population are found in the [PK Report, Post-text Table 14.2.1.1](#) and [Post-text Listing 16.2.6.2](#), respectively (Appendix 16.1.9). For the spaghetti plots of individual LB-102 and amisulpride concentrations versus time after a single oral dose LB-102 in Part A (SAD), see [PK Report, Post-text Figures 14.2.2.1](#) and [14.2.2.2](#). For the plots of individual LB-102 and amisulpride concentrations versus time for the PK Population in Part A (SAD), see [Post-text Figures 14.2.3.1](#) through [14.2.3.5](#).

Following administration of a single oral dose, LB-102 was rapidly absorbed and generally declined from peak in an apparent biphasic manner as shown in [Figure 4](#).

Amisulpride (< 5% minor metabolite) was formed quickly over time after a single dose of LB-102 and plasma concentrations of amisulpride generally declined with an approximate biphasic disposition ([PK Report, Figure 2](#)).



#### **11.4.1.1.2 Part B (MAD) Plasma Concentrations on Day 1 and After Multiple Doses**

Descriptive statistics and a listing of individual plasma LB-102 and amisulpride concentrations on Day 1 and after multiple doses for PK Population in Part B (MAD) are found in the [PK Report, Post-text Table 14.2.1.2](#) and [Post-text Listing 16.2.6.3](#). For the spaghetti plots of individual LB-102 and amisulpride concentrations versus time on Day 1 and after multiple doses for the PK Population in Part B (MAD), see [Post-text Figures 14.2.2.3](#) through [14.2.2.6](#). For the plots of individual LB-102 and amisulpride concentrations versus time for the PK Population in Part B (MAD), see [Post-text Figures 14.2.4.1](#) through [14.2.4.5](#).

Samples were collected for LB-102 on Day 1 at pre-dose, 15, 30, and 45 minutes, and 1, 1.5, 2, 3, 4, 6, 8, 12 hours post the first dose. The second dose of LB-102 was given at 12 hours post the first dose. Only pre-dose, 4, and 12 hours post the second dose was collected for the second dose of LB-102.

For LB-102 75 mg BID (Cohort 8), all subjects, with the exception of 1 (01S2092) who ended treatment on Day 3, had dosing terminated on Day 7 and extensive PK sampling occurred on Day 6 rather than Day 7. Subject 01S2092 had a total of 5 doses. For LB-102 100 mg BID (Cohort 7), 5 out of the 6 subjects had the last dose on Day 3 (5 total doses) and the remaining subject had their last dose on Day 2 (3 total doses). There were no extensive PK samples collected after treatment was terminated in this cohort.

As expected, exposures to LB-102 increased with increasing dose of LB-102, as shown in [Figure 5](#) and [Figure 6](#). Peak plasma concentrations of LB-102 were attained rapidly following the first dose of LB-102. Concentrations were relatively well maintained over the dosing interval. Amisulpride concentration similarly increased with increasing dose of LB-102 ([PK Report, Figure 6](#)).

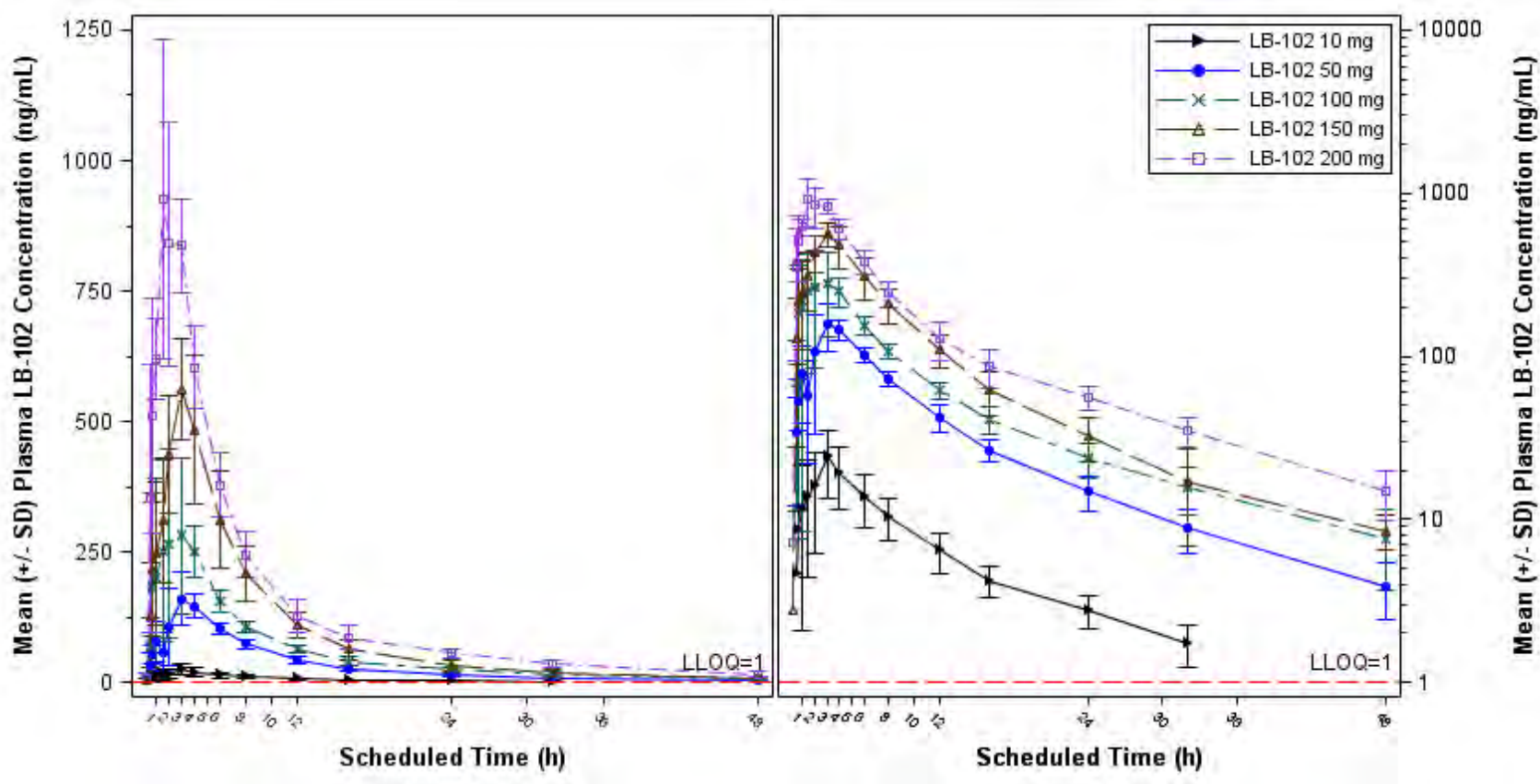
#### **11.4.1.1.3 Part B (MAD) Trough Plasma Concentrations**

Descriptive statistics and listings of individual plasma trough LB-102 and amisulpride concentrations are found in [PK Report, Post-text Table 14.2.1.2](#) and [Post-text Listing 16.2.6.3](#). For the spaghetti plots of individual trough LB-102 and amisulpride concentrations versus visit day for the PK Population in Part B (MAD), see [Post-text Figures 14.2.2.7](#) and [14.2.2.8](#).

For the plots of individual trough LB-102 and amisulpride concentrations versus visit day for the PK Population in Part B (MAD), see [Post-text Figures 14.2.4.6](#) through [14.2.4.8](#).

Trough concentrations of LB-102, as shown in [Figure 7](#), and amisulpride ([PK Report, Figure 8](#)) plateaued before the morning dose on Day 4 for LB-102 50 mg BID and LB-102 75 mg BID. However, there was a transient decrease of concentration for both LB-102 and amisulpride before the evening dose on Day 6 for subjects taking LB-102 75 mg BID.

**Figure 4: Plot of Mean ( $\pm$  SD) Plasma LB-102 Concentrations vs. Time by Treatment on Linear and Semi-Log Scale – PK Population: Part A (SAD)**

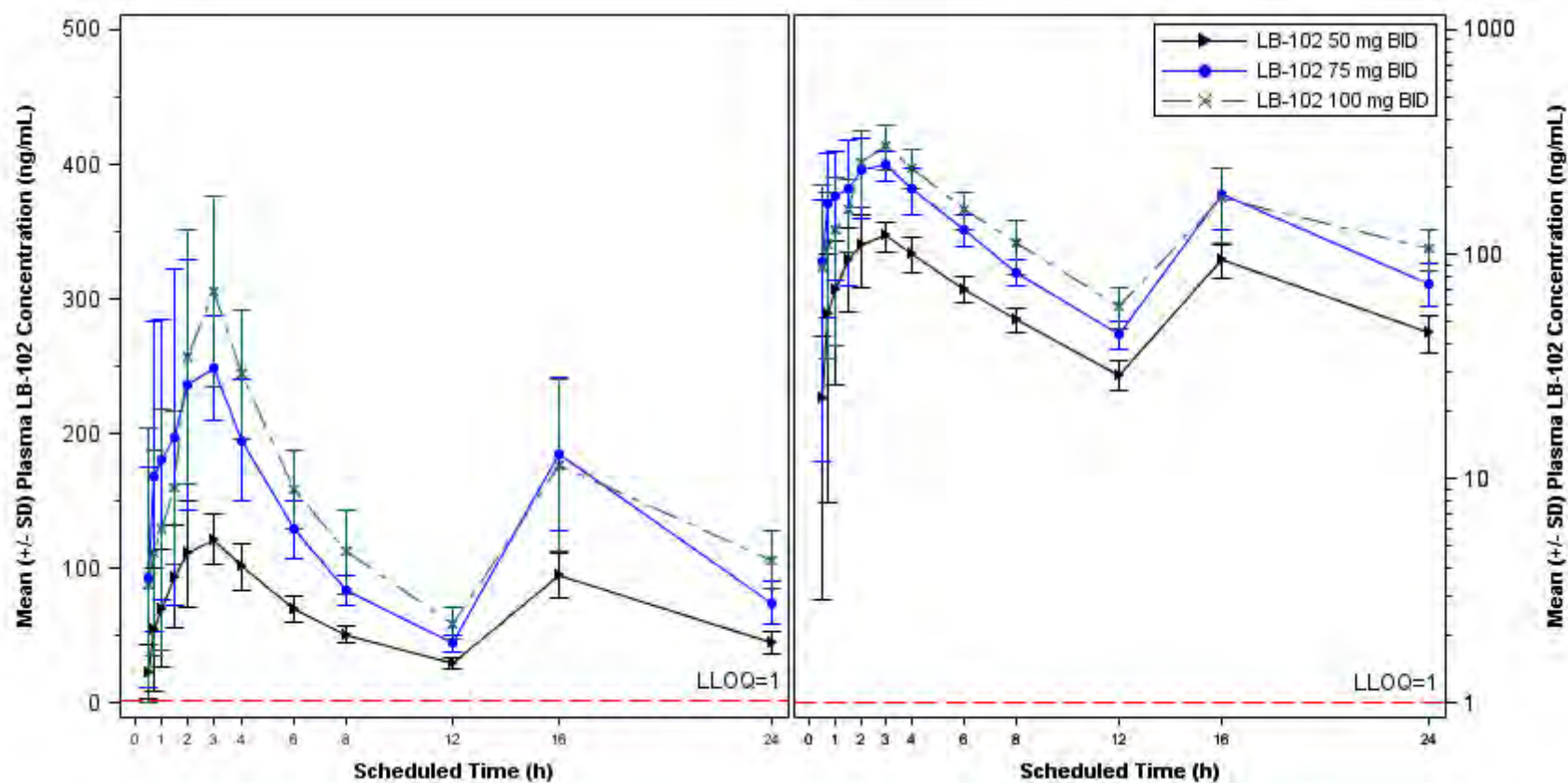


Note: Lower limit of quantitation for LB-102 = 1 ng/mL.

h = hours; SD = standard deviation.

Ref: PK Report, Post-text Figure 14.2.1.1.

**Figure 5: Plot of Mean ( $\pm$  SD) Plasma LB-102 Concentrations vs. Time on Day 1 by Treatment on Linear and Semi-Log Scale – PK Population: Part B (MAD)**

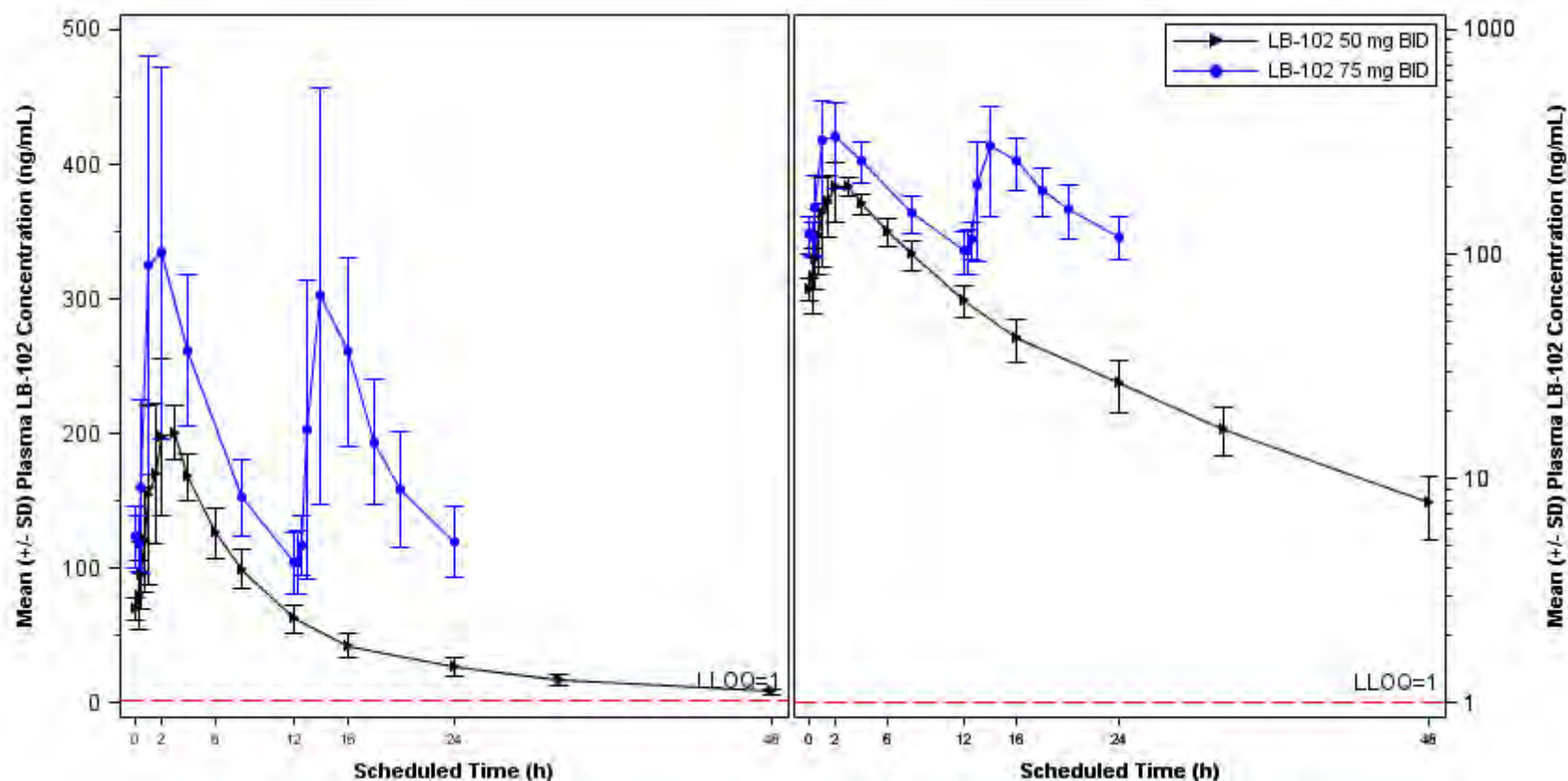


Note: Lower limit of quantitation for LB-102 = 1 ng/mL.

h = hours; SD = standard deviation.

Ref: [PK Report, Post-text Figure 14.2.1.3.](#)

**Figure 6: Plot of Mean ( $\pm$  SD) Plasma LB-102 Concentrations vs. Time after Multiple Doses by Treatment on Linear and Semi-Log Scale – PK Population: Part B (MAD)**



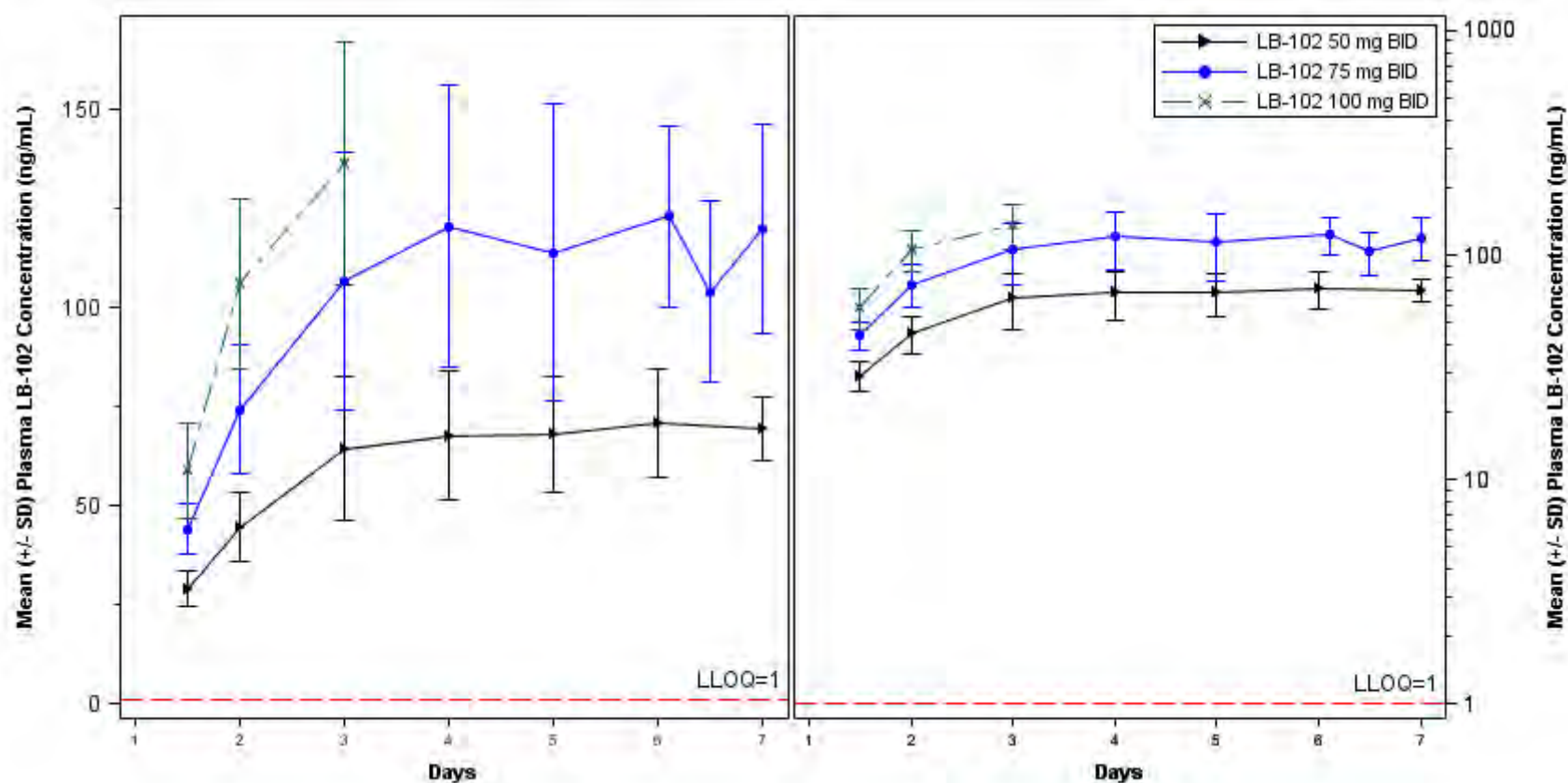
Note: Lower limit of quantitation for LB-102 = 1 ng/mL.

For Cohort 6 (LB-102 50 mg BID), the PK concentrations of the QD dosing on Day 7 were plotted. For Cohort 8 (LB-102 75 mg BID), the PK concentrations of both doses on Day 6 were plotted.

h = hours; SD = standard deviation.

Ref: PK Report, Post-text Figure 14.2.1.4.

**Figure 7: Plot of Mean ( $\pm$  SD) Plasma Trough LB-102 Concentrations vs. Visit Day by Treatment on Linear and Semi-Log Scale – PK Population: Part B (MAD)**



Note: Lower limit of quantitation for LB-102 = 1 ng/mL.

All pre-dose concentrations except that for the first dose on Day 1 were plotted as trough concentration.

h = hours; SD = standard deviation.

Ref: [PK Report, Post-text Figure 14.2.1.7.](#)



#### 11.4.1.2 Pharmacokinetics Parameters

For Part A (SAD), the PK parameters of LB-102 and amisulpride were derived using non-compartmental methods. PK parameters included  $AUC_{0-t}$ ,  $AUC_{0-24}$ ,  $AUC_{0-inf}$ ,  $AUC\%/extrap$ ,  $CL/F$ ,  $C_{max}$ ,  $T_{max}$ ,  $\lambda_z$ , and  $t_{1/2}$ .

For Part B (MAD), the PK parameters of LB-102 and amisulpride were calculated using the non-compartmental method after the first dose. The individual concentration data before the second dose on Day 1 were used for PK parameter calculation. PK parameters included  $AUC_{0-12, D1}$ ,  $AUC_{0-24, D1}$ ,  $AUC_{0-inf, D1}$ ,  $AUC\%/extrap, D1$ ,  $C_{max, D1}$ ,  $T_{max, D1}$ ,  $\lambda_z, D1$ , and  $t_{1/2, D1}$ . Additionally, using the non-compartmental method after the first dose, PK parameters of LB-102 and amisulpride were calculated using the individual concentration profiles on Day 7-9, or by comparing the PK parameters on Day 1 with Day 7. PK parameters included  $AUC_{0-12, D7}$ ,  $AUC_{0-inf, D7}$ ,  $AUC\%/extrap, D7$ ,  $C_{max, D7}$ ,  $T_{max, D7}$ ,  $\lambda_z, D7$ ,  $t_{1/2, D7}$ , the accumulation ratio based on  $C_{max}$  after the first dose and last dose ( $R_{C_{max}}$ ), accumulation ratio based on AUC after the first and last dose ( $R_{AUC}$ ), linearity index (LI), apparent clearance at steady state ( $CL_{ss}/F$ ), and dosing interval (Tau).

##### 11.4.1.2.1 Part A (SAD) Pharmacokinetics Parameters After a Single Oral Dose:

For the individual plasma parameters of LB-102 and amisulpride after a single dose of LB-102 for the PK Population, see [PK Report](#), [Post-text Table 14.2.2.1](#) and [Post-text Table 14.2.2.2](#), respectively.

PK parameters of LB-102 are listed in [Table 11](#). Systemic exposures to LB-102 generally increased with increasing dose and were somewhat variable, with GM CV% ranging from 11.7% to 45.6% for  $C_{max}$  and AUC values across treatment groups.  $CL/F$  appeared to decrease as dose increased.

Following administration of a single oral dose, LB-102 was rapidly absorbed, with mean peak plasma concentrations of LB-102 obtained within 3.01 hours post-dose (median  $T_{max}$  ranged from 1.75 to 3.01 hours). Plasma concentrations of LB-102 generally declined from peak in an apparent biphasic manner, with mean  $t_{1/2}$  ranged from 11.933 to 14.146 hours across treatment groups. Mean  $t_{1/2}$  did not appear to increase with increasing dose.

PK parameters of amisulpride are listed in [Table 12](#). Systemic exposures to amisulpride generally increased with increasing dose and were somewhat variable, with GM CV% ranging from 12.8% to 144.3% for  $C_{max}$  and AUC values across treatment groups.

Amisulpride was formed quickly over time after a single dose of LB-102 (median  $T_{max}$  ranged from 2 to 3.5 hours across treatment groups). Plasma concentrations of amisulpride generally declined with an approximate biphasic disposition with a mean  $t_{1/2}$  ranging from approximately 8.921 to 14.614 hours.

As a function of  $C_{max}$ , the percentage of amisulpride to LB-102 was on average about 2.5% across the doses, making amisulpride a minor metabolite of LB-102.

**Table 11: Summary of Key Plasma LB-102 PK Parameters After a Single Oral Dose for Part A (SAD) – PK Population**

Pharmacokinetics Parameter	Statistic	10 mg LB-102	50 mg LB-102	100 mg LB-102	150 mg LB-102	200 mg LB-102
$C_{\max}$ (ng/mL)	n	6	6	6	6	6
	Mean (SD)	24.1 (10.728)	176 (52.786)	348.167 (141.832)	596.5 (117.527)	975.667 (253.995)
	GM (GM CV%)	22.292 (44.5)	169.502 (30.8)	322.891 (45.6)	585.831 (21.7)	949.831 (25.4)
$T_{\max}$ (h)	n	6	6	6	6	6
	Median (min, max)	3 (3, 3)	3 (2, 4)	3.01 (1, 4)	3 (3, 4)	1.75 (1.5, 3)
$\lambda_z$ (1/h)	n	6	6	6	6	6
	Mean (SD)	0.054 (0.01411)	0.0592 (0.00877)	0.0521 (0.0136)	0.0591 (0.00945)	0.0569 (0.01591)
$T_{1/2}$ (h)	n	6	6	6	6	6
	Mean (SD)	13.675 (3.9375)	11.933 (1.7797)	14.146 (3.9617)	11.969 (1.8897)	12.997 (3.5854)
$AUC_{0-t}$ (ng·h/mL)	n	6	6	6	6	6
	Mean (SD)	221.911 (69.4093)	1526.08 (176.5906)	2636.04 (481.5386)	4490.161 (741.2812)	6709.821 (834.9332)
	GM (GM CV%)	212.353 (34.1)	1517.497 (11.7)	2594.86 (20.2)	4439.9 (16.5)	6668.19 (12.2)
$AUC_{0-24}$ (ng·h/mL)	n	6	6	6	6	6
	Mean (SD)	198.807 (66.9513)	1336.105 (167.6764)	2303.664 (533.1684)	4067.23 (685.9163)	5983.093 (833.9816)
	GM (GM CV%)	189.498 (35.1)	1327.048 (12.9)	2244.225 (26.5)	4019.483 (17)	5938.059 (13.3)
$AUC_{0-inf}$ (ng·h/mL)	n	6	6	6	6	6
	Mean (SD)	252.637 (69.857)	1595.938 (189.1599)	2809.785 (477.7622)	4636.577 (745.7299)	7002.109 (820.7252)
	GM (GM CV%)	244.171 (29.7)	1586.584 (11.9)	2773.559 (18.1)	4587.238 (16.1)	6962.173 (11.8)
CL/F (L/h)	n	6	6	6	6	6
	Mean (SD)	42.44 (12.598)	31.7 (3.794)	36.56 (6.935)	33.05 (5.25)	28.89 (3.381)

Note:  $GM\ CV\% = 100 \times (\exp[SD^2]-1)^{0.5}$ , where SD was the SD of the logarithm-transformed data.

$\lambda_z$  = apparent terminal elimination rate constant;  $AUC_{0-24}$  = area under the plasma concentration vs time curve from time 0 to 24 hours post-dose;  $AUC_{0-inf}$  = area under the plasma concentration vs time curve from time 0 to infinity;  $AUC_{0-t}$  = area under the plasma concentration vs time curve from time 0 to the last quantifiable concentration; CL/F = apparent clearance;  $C_{\max}$  = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; max = maximum; min = minimum; PK = pharmacokinetic(s); SD = standard deviation;  $t_{1/2}$  = apparent elimination half-life;  $T_{\max}$  = time to maximum plasma concentration.  
Ref: PK Report, Post-text Table 14.2.2.1.

**Table 12: Summary of Key Plasma Amisulpride PK Parameters After a Single Oral Dose for Part A (SAD) – PK Population**

Pharmacokinetics Parameter	Statistic	10 mg LB-102	50 mg LB-102	100 mg LB-102	150 mg LB-102	200 mg LB-102
$C_{\max}$ (ng/mL)	n	-	6	6	6	6
	Mean (SD)	-	4.167 (2.413)	7.648 (2.556)	17.283 (8.215)	27.747 (19.265)
	GM (GM CV%)	-	3.451 (83.6)	7.268 (37)	15.844 (47)	23.288 (72.1)
$T_{\max}$ (h)	n	-	6	6	6	6
	Median (min, max)	-	3 (2, 4)	3.5 (1.5, 4)	3 (2.05, 4)	2 (1.5, 3)
$\lambda_z$ (1/h)	n	-	-	-	5	5
	Mean (SD)	-	-	-	0.0815 (0.01976)	0.0501 (0.0131)
$t_{1/2}$ (h)	n	-	-	-	5	5
	Mean (SD)	-	-	-	8.921 (2.1572)	14.614 (3.7087)
$AUC_{0-t}$ (h•ng/mL)	n	-	6	6	6	6
	Mean (SD)	-	31.183 (19.6105)	68.34 (9.1123)	162.189 (64.5423)	247.397 (111.3574)
	GM (GM CV%)	-	22.378 (144.3)	67.808 (13.9)	152.936 (37.6)	220.341 (63.7)
$AUC_{0-24}$ (h•ng/mL)	n	-	1	4	5	5
	Mean (SD)	-	48.916 (-)	63.776 (8.2022)	152.976 (60.3055)	215.533 (94.741)
	GM (GM CV%)	-	48.916 (-)	63.386 (12.8)	144.481 (37)	194.768 (57.4)
$AUC_{0-inf}$ (h•ng/mL)	n	-	-	-	5	5
	Mean (SD)	-	-	-	188.552 (64.7283)	314.264 (88.0822)
	GM (GM CV%)	-	-	-	180.324 (33.8)	305.853 (25.5)

Note:  $GM\ CV\% = 100 \times (\exp[SD^2] - 1)^{0.5}$ , where SD was the SD of the logarithm-transformed data.

$\lambda_z$  = apparent terminal elimination rate constant;  $AUC_{0-24}$  = area under the plasma concentration vs time curve from time 0 to 24 hours post-dose;  $AUC_{0-inf}$  = area under the plasma concentration vs time curve from time 0 to infinity;  $AUC_{0-t}$  = area under the plasma concentration vs time curve from time 0 to the last quantifiable concentration;  $C_{\max}$  = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; max = maximum; min = minimum; PK = pharmacokinetic(s); SD = standard deviation;  $t_{1/2}$  = apparent elimination half-life;  $T_{\max}$  = time to maximum plasma concentration.

Ref: PK Report, Post-text Table 14.2.2.2.



#### 11.4.1.2.2 Part B (MAD) Pharmacokinetics Parameters After a Single Oral Dose and Multiple Oral Doses:

Table 13 summarizes the single dose and multiple doses plasma PK parameters for LB-102 by treatment for the PK Population. Systemic exposures ( $AUC_{0-inf, D1}$ ) to LB-102 generally increased with increasing dose.

After a single dose, LB-102 was rapidly absorbed, with a median time to maximum plasma concentration on Day 1 ( $T_{max, D1}$ ) ranging from 2.5 to 3 hours across dosing regimens. Compared with Part A (SAD), the mean half-life on Day 1 ( $t_{1/2, D1}$ ) was notably shorter, ranging from 3.974 to 4.171 hours across treatment groups. This observation was likely due to the limited PK sampling timepoints on Day 1 between the first and the second dose, which resulted in the true terminal elimination phase not being adequately characterized. This inadequate characterization may also explain the smaller  $AUC_{0-inf}$  values observed in Part B (MAD), compared with those in Part A (SAD) at the same dose level.

After multiple doses, peak exposure to LB-102 was higher than after a single dose (mean  $AUC_{0-12, D7}/AUC_{0-12, D1}$  [ $R_{Cmax}$ ] values ranged from 1.121 to 1.798). For  $R_{AUC}$ , there was a slightly more pronounced accumulation, with mean  $R_{AUC}$  ranging from 1.472 to 1.925. Apparent clearance after multiple doses appeared similar as dose increased.

Table 14 summarizes the single dose and multiple doses plasma PK parameters for amisulpride by treatment for the PK Population. Systemic exposures to amisulpride generally increased with increasing dose.

Amisulpride was quickly formed over time after a single dose of LB-102 with a median  $T_{max, D1}$  of 3 hours across treatment groups. However, not all parameters of amisulpride were assessed for the 50 mg LB-102 treatment group ( $\lambda_{z, D1}$ ,  $t_{1/2, D1}$ ,  $AUC_{0-24, D1}$ ,  $AUC_{0-inf, D1}$ ).

After multiple doses, median  $T_{max, D7}$  of amisulpride was ranged from 2.5 to 4 hours. Peak exposure to amisulpride was higher than after a single dose (mean  $R_{Cmax}$  values ranged from 1.317 to 2.016). For AUC, there was a slightly more pronounced accumulation, with mean  $R_{AUC}$  ranging from 1.801 to 2.232. Note that the total values of amisulpride were near the lower limit of quantification (LLOQ).

**Table 13: Summary of Single Dose and Multiple PK Parameters of LB-102 – PK Population: Part B (MAD)**

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Single Dose				
C <sub>max</sub> , D1 (ng/mL)	n	6	6	6
	Mean (SD)	125.467 (22.721)	267.333 (69.373)	325.167 (67.744)
	GM (GM CV%)	123.746 (18.4)	260.708 (24.2)	318.589 (23.2)
T <sub>max</sub> , D1 (h)	n	6	6	6
	Median (min, max)	2.5 (1.08, 3)	3 (2, 3.05)	2.5 (0.5, 3.02)
λ <sub>z</sub> , D1 (1/h)	n	4	6	5
	Mean (SD)	0.1673 (0.01581)	0.1768 (0.0234)	0.1715 (0.02768)
t <sub>1/2</sub> , D1 (h)	n	4	6	5
	Mean (SD)	4.171 (0.3951)	3.974 (0.4752)	4.121 (0.6106)
AUC <sub>0-12</sub> , D1 (h•ng/mL)	n	6	6	6
	Mean (SD)	787.967 (117.2242)	1524.015 (323.0305)	1783.039 (323.7988)
	GM (GM CV%)	780.718 (15)	1497.374 (20.5)	1760.632 (17.2)
AUC <sub>0-24</sub> , D1 (h•ng/mL)	n	4	6	5
	Mean (SD)	989.505 (98.5296)	1744.745 (315.2539)	2104.078 (428.5123)
	GM (GM CV%)	985.681 (10.3)	1722.519 (17.4)	2072.765 (19.1)
AUC <sub>0-inf</sub> , D1 (h•ng/mL)	n	4	6	5
	Mean (SD)	1012.649 (100.3718)	1777.932 (309.0153)	2152.886 (439.9467)
	GM (GM CV%)	1008.802 (10.2)	1757 (16.7)	2120.916 (19)
Multiple Dose				
C <sub>max</sub> , D7 (ng/mL)	n	6	5	-
	Mean (SD)	224 (39.8798)	309.4 (149.1452)	-
	GM (GM CV%)	221.115 (17.7)	287.044 (42.8)	-
T <sub>max</sub> , D7 (h)	n	6	5	-
	Median (min, max)	2.5 (1, 3)	2 (2, 4)	-
λ <sub>z</sub> , D7 (1/h)	n	6	-	-
	Mean (SD)	0.0514 (0.0137)	-	-
t <sub>1/2</sub> , D7 (h)	n	6	-	-
	Mean (SD)	14.311 (3.7449)	-	-
AUC <sub>0-12</sub> , D7 (h•ng/mL)	n	6	5	-
	Mean (SD)	1490.091 (130.1117)	2290.849 (708.461)	-
	GM (GM CV%)	1485.227 (8.9)	2215.515 (28.5)	-
AUC <sub>0-inf</sub> , D7 (h•ng/mL)	n	6	-	-
	Mean (SD)	2489.104 (312.4027)	-	-
	GM (GM CV%)	2471.525 (13.4)	-	-
CL <sub>ss</sub> /F (L/h)	n	6	5	-
	Mean (SD)	33.78 (3.082)	34.85 (8.792)	-

**Table 13: Summary of Single Dose and Multiple PK Parameters of LB-102 – PK Population (Continued)**

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Multiple Dose				
R <sub>Cmax</sub>	n	6	5	-
	Mean (SD)	1.798 (0.215)	1.121 (0.4118)	-
R <sub>AUC</sub>	n	6	5	-
	Mean (SD)	1.925 (0.3251)	1.472 (0.2833)	-
LI	n	4	5	-
	Mean (SD)	1.452 (0.1349)	1.254 (0.2246)	-

Note 1:  $GM\ CV\% = 100 * (\exp(SD^2) - 1)^{0.5}$ , where SD is the standard deviation of the log-transformed data.

Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the second dosing on Day 6.

$\lambda_z$  = apparent terminal elimination rate constant; AUC<sub>0-inf</sub> = area under the plasma concentration vs time curve from time 0 to infinity; AUC<sub>0-12</sub> = area under the plasma concentration vs time curve from time 0 to 12 hours; AUC<sub>0-24</sub> = area under the plasma concentration vs time curve from time 0 to 24 hours; BID = twice daily; CL<sub>ss</sub>/F = apparent clearance at steady state; C<sub>max</sub> = maximum plasma concentration; GM = geometric mean; h = hours; LI = linear index; max = maximum; min = minimum; PK = pharmacokinetic(s); QD = once daily; R<sub>AUC</sub> = accumulation ratio based on AUC after the first dose and last dose; R<sub>Cmax</sub> = accumulation ratio based on C<sub>max</sub> after the first dose and last dose; SD = standard deviation; t<sub>1/2</sub> = terminal elimination half-life; T<sub>max</sub> = time to maximum plasma concentration.

Ref: PK Report, Post-text Table 14.2.2.3, 14.2.2.4, and 14.2.2.5.

**Table 14: Summary of Single Dose and Multiple PK Parameters of  
Amisulpride – PK Population: Part B (MAD)**

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Single Dose				
C <sub>max</sub> , D1 (ng/mL)	n	6	6	6
	Mean (SD)	4.39 (1.475)	8.852 (4.187)	9.498 (3.122)
	GM (GM CV%)	4.17 (37.4)	8.229 (40.9)	9.154 (28.9)
T <sub>max</sub> , D1 (h)	n	6	6	6
	Median (min, max)	3 (1.5, 4)	3 (1.5, 3.05)	3 (2, 3.02)
λ <sub>z</sub> , D1 (1/h)	n	-	1	1
	Mean (SD)	-	0.1736 (-)	0.1542 (-)
t <sub>1/2</sub> , D1 (h)	n	-	1	1
	Mean (SD)	-	3.992 (-)	4.496 (-)
AUC <sub>0-12</sub> , D1 (h•ng/mL)	n	6	6	6
	Mean (SD)	30.316 (8.345)	55.681 (22.1069)	60.389 (17.6192)
	GM (GM CV%)	29.305 (29.7)	52.531 (37.5)	58.503 (27.4)
AUC <sub>0-24</sub> , D1 (h•ng/mL)	n	-	1	1
	Mean (SD)	-	107.364 (-)	111.611 (-)
	GM (GM CV%)	-	107.364 (-)	111.611 (-)
AUC <sub>0-inf</sub> , D1 (h•ng/mL)	n	-	1	1
	Mean (SD)	-	109.344 (-)	115.297 (-)
	GM (GM CV%)	-	109.344 (-)	115.297 (-)
Multiple Dose				
C <sub>max</sub> , D7 (ng/mL)	n	6	5	-
	Mean (SD)	8.505 (2.5169)	11.552 (6.4064)	-
	GM (GM CV%)	8.22 (28.6)	10.352 (54.2)	-
T <sub>max</sub> , D7 (h)	n	6	5	-
	Median (min, max)	2.5 (1.5, 3)	4 (2, 4)	-
λ <sub>z</sub> , D7 (1/h)	n	3	-	-
	Mean (SD)	0.0562 (0.01173)	-	-
t <sub>1/2</sub> , D7 (h)	n	3	-	-
	Mean (SD)	12.652 (2.3597)	-	-
AUC <sub>0-12</sub> , D7 (h•ng/mL)	n	6	5	-
	Mean (SD)	64.787 (13.2513)	102.153 (47.7293)	-
	GM (GM CV%)	63.779 (19.1)	94.201 (46.3)	-
AUC <sub>0-inf</sub> , D7 (h•ng/mL)	n	3	-	-
	Mean (SD)	133.815 (47.7073)	-	-
	GM (GM CV%)	128.265 (36.8)	-	-

Note 1: GM CV% = 100\*(exp(SD^2)-1)^0.5, where SD is the standard deviation of the log-transformed data.

Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the second dosing on Day 6.

λ<sub>z</sub> = apparent terminal elimination rate constant; AUC<sub>0-inf</sub> = area under the plasma concentration vs time curve from time 0 to infinity; AUC<sub>0-12</sub> = area under the plasma concentration vs time curve from time 0 to 12 hours; AUC<sub>0-24</sub> = area under the plasma concentration vs time curve from time 0 to 24 hours; BID = twice daily; C<sub>max</sub> = maximum plasma concentration; GM = geometric mean; h = hours; LI = linear index; max = maximum; min = minimum; PK = pharmacokinetic(s); QD = once daily; R<sub>AUC</sub> = accumulation ratio based on AUC after the first dose and last dose; R<sub>Cmax</sub> = accumulation ratio based on C<sub>max</sub> after the first dose and last dose; SD = standard deviation; t<sub>1/2</sub> = terminal elimination half-life; T<sub>max</sub> = time to maximum plasma concentration.

Ref: PK Report, Post-text Table 14.2.2.6, 14.2.2.7, and 14.2.2.8.

**Table 14: Summary of Single Dose and Multiple PK Parameters of Amisulpride – PK Population: Part B (MAD) (Continued)**

Day PK Parameter	Statistic	50 mg BID LB-102 (N=6)	75 mg BID LB-102 (N=6)	100 mg BID LB-102 (N=6)
Multiple Dose				
R <sub>Cmax</sub>	n	6	5	-
	Mean (SD)	2.016 (0.4953)	1.317 (0.5755)	-
R <sub>AUC</sub>	n	6	5	-
	Mean (SD)	2.232 (0.5958)	1.801 (0.4189)	-
LI	n	-	1	-
	Mean (SD)	-	1.173 (-)	-

Note 1:  $GM\ CV\% = 100 * (\exp(SD^2) - 1)^{0.5}$ , where SD is the standard deviation of the log-transformed data.

Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple doses were calculated using the PK concentration of the second dosing on Day 6.

$\lambda_z$  = apparent terminal elimination rate constant; AUC<sub>0-inf</sub> = area under the plasma concentration vs time curve from time 0 to infinity; AUC<sub>0-12</sub> = area under the plasma concentration vs time curve from time 0 to 12 hours; AUC<sub>0-24</sub> = area under the plasma concentration vs time curve from time 0 to 24 hours; BID = twice daily; C<sub>max</sub> = maximum plasma concentration; GM = geometric; h = hours; LI = linear index; max = maximum; min = minimum; PK = pharmacokinetic(s); QD = once daily; R<sub>AUC</sub> = accumulation ratio based on AUC after the first dose and last dose; R<sub>Cmax</sub> = accumulation ratio based on C<sub>max</sub> after the first dose and last dose; SD = standard deviation; t<sub>1/2</sub> = terminal elimination half-life; T<sub>max</sub> = time to maximum plasma concentration.

Ref: [PK Report](#), [Post-text Table 14.2.2.6](#), [14.2.2.7](#), and [14.2.2.8](#).

### 11.4.1.3 Dose Proportionality Analysis of LB-102 after a Single Oral Dose

#### 11.4.1.3.1 Part A (SAD)

Table 15 summarizes the preliminary analysis of dose proportionality for the PK Population for the 10, 50, 100, 150, and 200 mg LB-102 treatment groups. For all PK parameters tested ( $C_{\max}$ ,  $AUC_{0-t}$ , and  $AUC_{0-\infty}$ ), the 90% CI lower bound was slightly greater than unity, suggesting slightly greater than proportional increases in exposure with increases in dose.

**Table 15: Power Model Analysis of Dose Proportionality of LB-102 – PK Population**

PK Parameter Statistic	LB-102 Dose Level				
	10 mg LB-102 (N=6)	50 mg LB-102 (N=6)	100 mg LB-102 (N=6)	150 mg LB-102 (N=6)	200 mg LB-102 (N=6)
C <sub>max</sub> (ng/mL)					
n	6	6	6	6	6
GM (GM CV%)	22.292 (44.5)	169.502 (30.8)	322.891 (45.6)	585.831 (21.7)	949.831 (25.4)
Dose proportionality for C <sub>max</sub>					
n				30	
Slope estimate (SE)				1.22 (0.0564)	
90% CI				(1.12, 1.32)	
AUC <sub>0-t</sub> (h•ng/mL)					
n	6	6	6	6	6
GM (GM CV%)	212.353 (34.1)	1517.497 (11.7)	2594.86 (20.2)	4439.9 (16.5)	6668.19 (12.2)
Dose proportionality for AUC <sub>0-t</sub>					
n				30	
Slope estimate (SE)				1.12 (0.0358)	
90% CI				(1.06, 1.19)	
AUC <sub>0-inf</sub> (h•ng/mL)					
n	6	6	6	6	6
GM (GM CV%)	244.171 (29.7)	1586.584 (11.9)	2773.559 (18.1)	4587.238 (16.1)	6962.173 (11.8)
Dose proportionality for AUC <sub>0-inf</sub>					
n				30	
Slope estimate (SE)				1.09 (0.0324)	
90% CI				(1.04, 1.15)	

Note: The power model was estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model was fitted by restricted maximum likelihood (REML) using SAS Proc Mixed.

$AUC_{0-\infty}$  = area under the plasma concentration vs time curve from time 0 to infinity;  $AUC_{0-t}$  = area under the plasma concentration vs time curve from time 0 to the last quantifiable concentration; CI = confidence interval;  $C_{\max}$  = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; PK = pharmacokinetic(s); SE = standard error.

Ref: [PK Report](#), [Post-text Table 14.2.3.1](#).

#### 11.4.1.3.2 Part B (MAD)

Table 16 summarizes the exploratory analysis of dose proportionality using a power model for  $C_{\max, D1}$ ,  $AUC_{0-12, D1}$ , and  $AUC_{0-inf, D1}$  after the first dose on Day 1 and for  $C_{\max, D7}$  and  $AUC_{0-12, D7}$  after multiple doses for the PK Population.

For  $C_{\max, D1}$  after a single dose of LB-102, the 90% CI lower bound for  $C_{\max, D1}$  was slightly greater than unity (1.06 - 1.73), suggesting slightly greater than proportional increases in  $C_{\max, D1}$  with increases in dose. For  $AUC_{0-12, D1}$  and  $AUC_{0-inf, D1}$  after a single dose of LB-102, the 90% CI for  $AUC_{0-12, D1}$  (0.93 - 1.48) and  $AUC_{0-inf, D1}$  (0.79 - 1.37) contained unity, suggesting proportional increases in  $AUC_{0-12, D1}$  and  $AUC_{0-inf, D1}$  with increases in dose.

For  $C_{\max, D7}$  and  $AUC_{0-12, D7}$  after multiple doses of LB-102, the 90% CI for both PK parameters contained unity (-0.19 - 1.47 and 0.44 - 1.53, respectively), suggesting proportional increases in  $C_{\max, D7}$  and  $AUC_{0-12, D1}$  with increases in dose.

**Table 16: Power Model Analysis of Dose Proportionality of LB-102 – PK Population**

PK Parameter Statistic	LB-102 Dose Level		
	50 mg LB-102 (N=6)	75 mg LB-102 (N=6)	100 mg LB-102 (N=6)
Single Dose			
C <sub>max</sub> , D1 (ng/mL)			
n	6	6	6
GM (GM CV%)	123.746 (18.4)	260.708 (24.2)	318.589 (23.2)
Dose proportionality for C <sub>max</sub> , D1			
n			18
Slope estimate (SE)			1.4 (0.192)
90% CI			(1.06, 1.73)
AUC <sub>0-12</sub> , D1 (h•ng/mL)			
n	6	6	6
GM (GM CV%)	780.718 (15)	1497.374 (20.5)	1760.632 (17.2)
Dose proportionality for AUC <sub>0-12</sub> , D1			
n			18
Slope estimate (SE)			1.2 (0.1584)
90% CI			(0.93, 1.48)
AUC <sub>0-inf</sub> , D1 (h•ng/mL)			
n	4	6	5
GM (GM CV%)	1008.802 (10.2)	1757 (16.7)	2120.916 (19)
Dose proportionality for AUC <sub>0-inf</sub> , D1			
n			15
Slope estimate (SE)			1.08 (0.1614)
90% CI			(0.79, 1.37)
Multiple Dose			
C <sub>max</sub> , D7 (ng/mL)			
n	6	5	-
GM (GM CV%)	221.115 (17.7)	287.044 (42.8)	-
Dose proportionality for C <sub>max</sub> , D7			
n			11
Slope estimate (SE)			0.64 (0.4525)
90% CI			(-0.19, 1.47)
AUC <sub>0-12</sub> , D7 (h•ng/mL)			
n	6	6	-
GM (GM CV%)	1485.227 (8.9)	2215.515 (28.5)	-
Dose proportionality for AUC <sub>0-12</sub> , D7			
n			11
Slope estimate (SE)			0.99 (0.2959)
90% CI			(0.44, 1.53)

Note 1: The power model was estimated by regressing the ln-transformed PK parameter on ln-transformed dose. The power model was fitted by restricted maximum likelihood (REML) using SAS Proc Mixed.

Note 2: For Cohort 6 (LB-102 50 mg BID), the PK parameters after multiple dose were calculated using the PK concentration of the QD dosing on Day 7. For Cohort 8 (LB-102 75 mg BID), the PK parameters after multiple dose were calculated using the PK concentration of the 2nd dosing on Day 6.

$AUC_{0-12}$  = area under the plasma concentration vs time curve from time 0 to 12 hours;  $AUC_{0-inf}$  = area under the plasma concentration vs time curve from time 0 to infinity; BID = twice daily; CI = confidence interval;  $C_{\max}$  = maximum plasma concentration; CV = coefficient of variation; GM = geometric mean; h = hours; PK = pharmacokinetic(s); QD = once daily; SE = standard error.

Ref: [PK Report](#), [Post-text Table 14.2.3.2](#).



### 11.4.2 Statistical/Analytical Issues

No subjects or data were excluded from statistical analysis ([Appendix 16.1.9](#)). If a deviation from procedures described in the protocol, that impacted the quality of data required to meet the objectives of the study occurred, they would have been documented and would have resulted in exclusion of PK data from the analyses for a particular subject. This analysis plan included any deviations or events that would invalidate the evaluation of the PK. Examples of deviations and events which could have resulted in exclusion of PK data from the analyses included emesis after dosing (within the predetermined time), sample processing or assay errors that led to inaccurate bioanalytical results. Other deviations or events, which did not disqualify data from analyses, might have required minor adjustments to calculations. If these occurred, data analyses were adjusted and documented accordingly such that conclusions were not biased. An example of such an event included, but was not limited to, minor deviations between the actual and scheduled time of sample collection. Minor deviations between the actual and the scheduled time of PK blood sampling occurred and are found in the individual listings provided in the [PK Report](#) ([Appendix 16.1.9](#)).

#### 11.4.2.1 Adjustments for Covariates

Not applicable.

#### 11.4.2.2 Handling of Missing Data or Concentration below the Lower Limit of Quantification

There were no reported missing sampling times for this study with the exception of 1 subject (01S0119, 200 mg LB-102 QD) without a PK sample on Day 1, 12 hours post-dose ([Data Listing 16.2.2](#)). However, it was planned that if the actual sampling time was missing, but a valid concentration value had been measured, the concentration value would have been flagged and the scheduled time point might be used for the calculation of PK parameters.

There were no cases of missing pre-dose sampling. However, if there were cases of missing pre-dose on Day 1 (Part A or Part B), the missing components would have been assumed as zero. If there were cases of missing pre-dose on Day 7 in Part B, the minimum observed concentration during the dosing interval (dosing on Day 7 until 12 hours after dosing) would have been used as pre-dose concentration values. For the other cases, the missing data would not have been imputed.

The following rules were used to handle concentration below the lower limit of quantification (BLQ) for the PK parameter calculation and individual concentration data:

- If one or more BLQ values occurred before the first measurable concentration, they were assigned as zero concentration for single dose (Part A and the first dose of Part B) and as the LLOQ for multiple dose (other than the first dose of Part B).
- If BLQ values occurred between measurable concentrations or after the last measurable concentration in a profile, the BLQ was omitted (set to missing).

The following general rules were applied for the concentration summary (including tabulation and plotting):

- Mean concentrations at any individual time point were only calculated if at least half of the subjects had valid values (i.e. quantifiable and not missing) at this time point for each treatment.
- In cases where a mean value was not calculated, due to the above criterion not being met, the mean value was set to missing for mean plotting purposes.
- BLQ was set to zero for the calculation of these mean values. The only exception was that the BLQ at pre-dose or before the last quantifiable measurement for multiple dose (other than Part A and the first dose of Part B) was imputed as LLOQ for multiple doses.

#### 11.4.3 Tabulation of Individual Response Data

Individual subject listings for PK results are provided in [Section 12.2](#) of the PK Report (Appendix 16.1.9).

#### 11.4.4 Discussion of Pharmacokinetics Results

In Part A (SAD), LB-102 was rapidly absorbed and LB-102 concentration generally declined from peak in an apparent biphasic manner. The estimates of mean  $t_{1/2}$  of LB-102 generally ranged from 11.993 to 14.146 hours; exposure (as measured by  $C_{max}$ ,  $AUC_{0-t}$ , and  $AUC_{0-inf}$ ) increased in a slightly greater than dose-proportional manner. Apparent clearance ( $CL/F$ ) appeared to decrease as dose increased. Amisulpride was formed quickly over time after a single dose of LB-102 and generally declined with an approximate biphasic disposition.

In Part B (MAD), extensive PK sampling occurred on Day 6 rather than Day 7 and the last dose was given on Day 7. This was done to capture sufficient data points in the second dose of BID dosing to conduct the PK analysis. Thus, the PK profile for the second dose on Day 6 (including the pre-dose on Day 7) was used to calculate the PK parameter after multiple doses. For the calculation of  $AUC_{0-12, D1}$ , the actual time for the 12-hour sample was used in place of the nominal 12 hour since the concentration at 12 hours post-dose could not be predicted.

In Part B (MAD), trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4. After multiple doses, there was slight to moderate accumulation of LB-102 across dose levels with mean  $R_{C_{max}}$  values ranged from 1.121 to 1.798 and with mean  $R_{AUC}$  values ranged from 1.472 to 1.925. Amisulpride had a higher accumulation than LB-102 across dose levels with mean  $R_{C_{max}}$  values ranged from 1.317 to 2.016 and with mean  $R_{AUC}$  values ranged from 1.801 to 2.232. Exposure (as measured by  $C_{max, D7}$  and  $AUC_{0-12, D7}$ ) to LB-102 increased in a dose proportional manner. Apparent clearance at steady state ( $CL_{ss}/F$ ) to LB-102 appeared to be similar as dose increased.

#### 11.4.5 Pharmacokinetics Conclusions

In Part A (SAD), LB-102 was rapidly absorbed and LB-102 concentration generally declined from peak in an apparent biphasic manner. Exposure increased in a slightly greater than dose-proportional manner. Apparent clearance appeared to decrease as dose increased. Amisulpride was formed quickly over time after a single dose of LB-102 and generally declined with an approximate biphasic disposition of comparable shape to LB-102 but at approximately 2.5% of LB-102

abundance. The plasma concentrations of amisulpride at lower doses were within several fold of LLOQ making descriptive PK analysis tenuous. In fact, amisulpride was not detected in subjects taking 10 mg LB-102 QD (Cohort 2). In vitro studies suggest equal pharmacological potency between LB-102 and amisulpride, but since amisulpride is present at 2.5% LB-102 concentration, it thus represents a minor active metabolite (defined as either less than 10% parent concentration or less than 10% of total pharmacological activity).

In Part B (MAD), trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4. After multiple doses, there was slight to moderate accumulation of LB-102 across dose levels. Amisulpride had a higher accumulation ( $R_{C_{max}}$  and  $R_{AUC}$ ) than LB-102 across dose levels. Exposure to LB-102 increased in a dose proportional manner. Apparent clearance at steady state to LB-102 appeared to be similar as dose increased.

## 12. SAFETY EVALUATION

### 12.1 Extent of Exposure

A total of 64 subjects were randomized into the study, with 48 receiving at least one dose of LB-102 and 16 receiving placebo ([Table 14.1.1](#)). There were 8 cohorts of subjects, with 6 subjects in each, receiving either a single dose (Part A, Cohorts 1-5) or multiple doses of LB-102 (Part B, Cohorts 6-8) and with 2 subjects in each cohort receiving placebo. The extent of exposure of LB-102 for each cohort is listed below and is provided in [Data Listing 16.2.5](#).

#### 12.1.1 Part A (SAD)

All subjects in Cohorts 1-5 received a single oral dose of LB-102 on Day 1. Cohort 1 received a single dose of 50 mg LB-102 (N=6) or placebo (N=2). Cohort 2 received a single dose of 10 mg LB-102 (N=6) or placebo (N=2). Cohort 3 received a single dose of 100 mg LB-102 (N=6) or placebo (N=2). Cohort 4 received a single dose of 200 mg LB-102 (N=6) or placebo (N=2). Cohort 5 received a single dose of 150 mg LB-102 (N=6) or placebo (N=2).

All subjects in each cohort completed treatment and were discharged on Day 3. Subjects in Cohorts 1-4 returned for a follow-up visit on Day 8 and subjects in Cohort 5 returned on Day 15.

#### 12.1.2 Part B (MAD)

It was planned that subjects in Cohorts 6-8 would receive twice daily doses of LB-102, or placebo on Days 1-6 and one dose on Day 7. Cohort 6 received twice daily doses of 50 mg (100 mg/day) LB-102 (N=6) or placebo (N=2) on Days 1-6 and once on Day 7. It was planned that Cohort 7 would receive twice daily doses of 100 mg (200 mg/day) LB-102 (N=6) or placebo (N=2) on Days 1-6 and once on Day 7, but no subject completed the treatment course due to a stopping criterion being met on Day 3. Cohort 8 received twice daily doses of 75 mg (150 mg/day) LB-102 (N=6) or placebo (N=2) on Days 1-6 and once on Day 7, with the exception of one subject receiving LB-102 who ended treatment on Day 3.

All subjects in Cohort 6 completed the treatment course, were discharged on Day 9, and returned for a follow-up visit on Day 15.

No subject in Cohort 7 completed the treatment course because one subject (01S2069) withdrew from the study after receiving their morning dose on Day 2 for personal/family reasons and because 2 subjects (01S2066 and 01S2079) each had an acute dystonic reaction on Day 3. These TEAEs met a stopping criterion for the cohort from having at least two TEAEs in the same organ class. Treatment was halted for all subjects in Cohort 7, including the two subjects receiving placebo. Therefore, 7 out of 8 subjects in this cohort received doses of 100 mg LB-102 (N=5) or placebo (N=2) twice daily on Days 1-2 and QD on Day 3, totaling 5 doses. Subject 01S2069 received twice daily doses of 100 mg LB-102 on Day 1 and one dose on Day 2, totaling 3 doses.

In Cohort 8, 5 out of 8 subjects completed the treatment course, were discharged on Day 9, and returned for a follow-up visit on Day 15. The one subject (01S2092) who did not complete the treatment course received twice daily doses of 75 mg LB-102 on Days 1-2 and one dose on Day 3 before treatment was halted due to an AE (acute dystonic reaction). This subject withdrew consent from the study the following day.

## 12.2 Adverse Events

### 12.2.1 Brief Summary of Adverse Events

Out of the 64 subjects, 28 subjects (50 mg QD, N=4; 10 mg QD, N=2; 100 mg QD, N=3; 200 mg QD, N=3; 150 mg QD, N=1; 50 mg BID, N=2; 100 mg BID, N=3; 75 mg BID, N=5; Placebo, N=5) experienced at least one treatment-emergent adverse event (TEAE), with a total of 43 TEAEs. TEAEs were defined as any AE that occurred after the first study treatment (LB-102 or placebo). Out of the 43 TEAEs, 29 (50 mg QD, 3; 10 mg QD, 1; 100 mg QD, 3; 200 mg QD, 5; 150 mg QD, 1; 50 mg BID, 2; 100 mg BID, 5; 75 mg BID, 8; Placebo, 1) were considered possibly or probably or definitely related to treatment. All TEAEs were mild or moderate intensity (37 mild, 6 moderate) as individually described in [Data Listing 16.2.7](#). The number of subjects with TEAEs and the number of TEAEs, are displayed in [Table 17](#) and [Table 18](#), respectively. TEAEs separated by organ class, severity, and/or relationship to study drug are found in [Statistical Tables 14.3.1.3](#) to [14.3.1.5](#).

No TEAE led to study discontinuation ([Statistical Table 14.3.1.6](#)). Three (3) subjects receiving 100 mg LB-102 BID (Cohort 7) withdrew consent from the study for personal/family or work issues, and 2 out of these 3 subjects experienced acute dystonic reaction, but withdrew consent prior to reporting their TEAE and the remaining subjects (N=3 LB-102; N=2 Placebo) in this cohort discontinued drug administration because a stopping criterion was met. One (1) subject receiving 75 mg LB-102 BID (Cohort 8) experienced acute dystonic reaction on Day 3, and they voluntarily withdrew consent the following day.

Of the TEAEs definitely related to study drug, there were 11 cases of elevated prolactin ( $\geq 100$   $\mu\text{g/L}$ ; 50 mg QD, N=3; 10 mg QD, N=1; 100 mg QD, N=1; 150 mg QD, N=1; 50 mg BID, N=2; 100 mg BID, N=1; 75 mg BID, N=2), 4 cases of moderate dystonia (200 mg QD, N=1; 100 mg BID, N=2; 75 mg BID, N=1), and 1 case of mild ECG QTcF prolongation (41 msec, 200 mg LB-102 QD) that all resolved. Of the TEAEs considered probably or possibly related to study drug, there were at least one case of nausea (01S0073, 100 mg LB-102 QD; 01S0120, 200 mg LB-102 QD; 01S2079, 100 mg LB-102 BID; 01S2093, 75 mg LB-102 BID), vomiting (01S2079, 100 mg LB-102 BID), urticaria (01S0063, 100 mg LB-102 QD), gastroesophageal

disease (01S0120, 200 mg LB-102 QD), insomnia (01S0120, 200 mg LB-102 QD; 01S2102, 75 mg LB-102 BID), dizziness (01S2093, 75 mg LB-102 BID), migraine (01S2079, 100 mg LB-102 BID), and somnolence (01S2093, 75 mg LB-102 BID) in subjects taking LB-102 ([Statistical Table 14.3.1.5](#)). Note that some subjects experienced multiple TEAEs ([Data Listing 16.2.7](#)).

**Table 17: Number of Subjects with TEAEs**

Category		Part A (SAD)					Part B (MAD)			Placebo
		Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5	Cohort 6	Cohort 7	Cohort 8	
	N	6	6	6	6	6	6	6	6	
With at Least One AE	Yes	4 (66.7%)	2 (33.3%)	3 (50.0%)	3 (50.0%)	1 (16.7%)	2 (33.3%)	3 (50.0%)	5 (83.3%)	5 (31.3%)
	No	2 (33.3%)	4 (66.7%)	3 (50.0%)	3 (50.0%)	5 (83.3%)	4 (66.7%)	3 (50.0%)	1 (16.7%)	11 (68.8%)
With at Least One Mild or Moderate AE	N	4	2	3	3	1	2	3	5	5
	Yes	4 (100.0%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	1 (100.0%)	2 (100.0%)	3 (100.0%)	5 (100.0%)	5 (100.0%)
	No	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
With at Least One Severe AE	N	4	2	3	3	1	2	3	5	5
	Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	No	4 (100.0%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	1 (100.0%)	2 (100.0%)	3 (100.0%)	5 (100.0%)	5 (100.0%)
With at Least One Not Related or Unlikely Related AE	N	4	2	3	3	1	2	3	5	5
	Yes	2 (50.0%)	1 (50.0%)	1 (33.3%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (20.0%)	4 (80.0%)
	No	2 (50.0%)	1 (50.0%)	2 (66.7%)	1 (33.3%)	1 (100.0%)	2 (100.0%)	2 (66.7%)	4 (80.0%)	1 (20.0%)
With at Least One Possibly or Probably or Definitely Related AE	N	4	2	3	3	1	2	3	5	5
	Yes	3 (75.0%)	1 (50.0%)	2 (66.7%)	3 (100.0%)	1 (100.0%)	2 (100.0%)	3 (100.0%)	5 (100.0%)	1 (20.0%)
	No	1 (25.0%)	1 (50.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (80.0%)

Ref: [Statistical Table 14.3.1.1](#)

**Table 18: Number of TEAEs**

Category	Part A (SAD)					Part B (MAD)			Placebo
	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5	Cohort 6	Cohort 7	Cohort 8	
Adverse Event	5	2	4	8	1	2	7	9	5
Mild or Moderate Adverse Event	5	2	4	8	1	2	7	9	5
Severe Adverse Event	0	0	0	0	0	0	0	0	0
Serious Adverse Event	0	0	0	0	0	0	0	0	0
Not Related or Unlikely Related Adverse Event	2	1	1	3	0	0	2	1	4
Possibly or Probably or Definitely Related Adverse Event	3	1	3	5	1	2	5	8	1

Ref: [Statistical Table 14.3.1.2.](#)

### 12.2.2 Display of Adverse Events

TEAEs are displayed in the following tables:

- [Table 17](#) and [Statistical Table 14.3.1.1](#) summarizes the number of subjects with TEAEs.
- [Table 18](#) and [Statistical Table 14.3.1.2](#) summarizes the number of TEAEs.
- [Statistical Table 14.3.1.3](#) summarizes the number of subjects with TEAEs by Medical dictionary for regulatory activities (MedDRA) system organ class / preferred term.
- [Statistical Table 14.3.1.4](#) summarizes the number of subjects with TEAEs by MedDRA system organ class / preferred term and severity.
- [Statistical Table 14.3.1.5](#) summarizes the number of subjects with TEAEs by MedDRA system organ class / preferred term and the relationship to study drug.
- [Statistical Table 14.3.1.6](#) summaries the AEs leading to discontinuation.

### 12.2.3 Analysis of Adverse Events

In subjects receiving 50 mg LB-102 QD (Cohort 1), 3 of the 5 TEAEs were increased blood prolactin (01S0002, 01S0003, 01S0004) that were determined definitely related to study drug, 1 TEAE of diarrhea (01S0003) was unlikely related, and 1 TEAE of upper respiratory tract infection (01S0005) was unrelated. All TEAEs resolved and there were no actions taken.

In subjects receiving 10 mg LB-102 QD (Cohort 2), one of the two TEAEs was increased blood prolactin (01S0030) that was definitely related to LB-102 and one was abdominal pain (01S0042) that was considered unrelated to LB-102. All TEAEs resolved and there were no actions taken.

In subjects receiving 100 mg LB-102 QD (Cohort 3), one of the four TEAEs was increased blood prolactin (01S0063) that was definitely related to study drug, one was nausea (01S0073) that was probably related, one was urticaria (01S0063) that was possibly related, and one was an upper respiratory tract infection (01S0071) that was unrelated. Subject 01S0071 took Nyquil on 22 February 2020 (Day 5) for treatment related to an upper respiratory tract infection that occurred from 21 February 2020 to 27 February 2020. Subject 01S0063 took cetirizine on 18 February 2020 (Day 1) for the treatment of urticaria that occurred on 18 February 2020. All TEAEs resolved.

In subjects receiving 200 mg LB-102 QD (Cohort 4), 2 of the 8 TEAEs were considered definitely related (1 ECG QTcF prolonged 41 msec, 01S0116; 1 dystonia, 01S0119), one was probably related (insomnia, 01S0120), two were possibly related (gastroesophageal reflux disease and nausea, 01S0120), one was unlikely related (heart palpitations, 01S0119), and two were unrelated (1 headache and oropharyngeal pain, 01S0120). Subject 01S0116's prolonged ECG QTcF (41 msec) was considered to be of mild severity. Subject 01S0119 was treated with diphenhydramine as well as benztropine on 03 March 2020 (Day 1) for treatment of acute dystonia that occurred after taking LB-102. All other TEAEs resolved and there were no actions taken.



In subjects receiving 150 mg LB-102 QD (Cohort 5), there was one TEAE for a mild increase in blood prolactin (01S0157) that was definitely related to LB-102. This TEAE resolved and no action was taken.

In subjects receiving 50 mg LB-102 BID (Cohort 6), there were two TEAEs for mild increases in blood prolactin (01S2050 and 01S2053) that were definitely related to LB-102. The TEAEs resolved and no actions were taken.

In subjects receiving 100 mg LB-102 BID (Cohort 7), 3 out of the 7 TEAEs were definitely related to study drug (1 mild increase in blood prolactin, 01S2069; 2 moderate cases of dystonia, 01S2066 and 01S2079), 1 was probably related (nausea, 01S2079), one was possibly related (vomiting, 01S2079), and two were unrelated (1 dry mouth, 01S2066; 1 somnolence, 01S2066). LB-102 was withdrawn in subjects 01S2066 and 01S2079 and the dystonia resolved. Subject 01S2066 was given benztropine, methylprednisolone, and promethazine on 04 June 2020 (Day 3) for the treatment of the dystonia that occurred after the morning dose. Subject 01S2079 was given acrivastine and ondansetron on 04 June 2020 (Day 3) for the treatment of the dystonia that similarly occurred after the morning dose. All other TEAEs resolved without action taken.

In subjects receiving 75 mg LB-102 BID (Cohort 8), 3 out of the 9 TEAEs were definitely related to study drug (2 mild increases in blood prolactin, 01S2080 and 01S2094; 1 moderate case of dystonia, 01S2092), 3 were probably related (nausea, dizziness, and somnolence, 01S2093), 2 were possibly related (1 migraine, 01S2092; 1 insomnia, 01S2102), and 1 was unrelated (back pain, 01S2102). LB-102 was withdrawn from subject 01S2092 and the subject was given benztropine, promethazine, and ibuprofen on June 25<sup>th</sup>, 2020 (Day 3). The dystonia resolved. All other TEAEs resolved and the dose of LB-102 was not changed.

In the Placebo group, one out of the five TEAEs was probably related to study drug (headache, 01S0068) and 4 were unrelated (1 abdominal pain, 01S2082; 1 arthropod bite, 01S2095; 1 back pain, 01S0169; 1 dizziness, 01S2047). Subject 01S0068 was given paracetamol on February 19<sup>th</sup>, 2020 (Day 2). All TEAEs resolved and the dose was not changed.

#### **12.2.4 Listing of Adverse Events**

Listing of TEAEs by subject is found in [Data Listing 16.2.7](#).

### **12.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events**

There were no deaths or other serious AEs. There were 4 cases of dystonia and 1 case of prolonged QTcF interval as described in [Section 12.3.2](#). The 11 cases of elevated prolactin are described in [Section 12.4.1](#).

#### **12.3.1 Listing of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events**

##### **12.3.1.1 Deaths**

No deaths occurred during the study.

### 12.3.1.2 Other Serious Adverse Events

No serious adverse events occurred during the study.

### 12.3.1.3 Other Significant Adverse Events

There were no separate listings for the significant TEAEs. The 4 cases of dystonia, 1 case of prolonged QTcF interval, and 11 cases of elevated prolactin.

### 12.3.2 Narratives of Deaths, Other Serious Adverse Events, and Certain Other Significant Adverse Events

Subject 01S0116 (31-year-old female) was randomized and enrolled on 02 March 2020 and received 200 mg LB-102 QD in Cohort 4. The subject experienced a QTcF prolongation (41 msec) 2 hours after the first dose (09:42, 03 March 2020) that was definitely related to study drug. This value was confirmed by an unscheduled ECG measurement 1 minute later. The QTcF prolongation resolved by 4 hours post-dose (11:42) without any concomitant medications. The QTcF intervals at each time point for this subject are listed in the Table 19 below.

**Table 19: QTcF Intervals Over Time for Subject 01S0116**

Visit	QTcF Interval, msec
Day -28 to -1	416.6
Day 0	432.6
Day 1, Pre-dose	417
Day 1, 2 hours Post-dose	458
Day 1, 4 hours Post-dose	437.9
Day 1, 6 hours Post-dose	430.1
Day 2, 24 hours Post-dose	415.7

Subject 01S0119 (20-year-old male) was randomized and enrolled on 03 March 2020 and received 200 mg LB-102 QD in Cohort 4. The subject experienced an acute dystonic reaction on Day 1 (03 March 2020) that was definitely related to study drug. The acute dystonia diagnosis was confirmed by an emergency room doctor and the subject was given benztropine at 19:01 and diphenhydramine at 20:52 the same day. On the same day (03 March 2020), this subject also experienced a cardiac disorder (mild palpitations) that was considered unlikely related to study drug. However, QTcF increased 39.7 msec from baseline at 2 hours post-dose and 23.8 msec at 4 hours post-dose (pre-dose= 363 msec; 2 hours post-dose= 402.7 msec; 4 hours post-dose = 386.8 msec). This prolongation did not meet the criteria to be classified as a TEAE because QTcF was not >450 msec.

Subject 01S2066 (37-year-old male) was randomized and enrolled on 02 June 2020 and received 100 mg LB-102 BID in Cohort 7. The subject experienced a Grade 2 TEAE of acute dystonic reaction on Day 3 (04 June 2020) starting one-hour post morning dose and worsened by four hours post-dose. This reaction was considered definitely related to LB-102. Unscheduled chemistry laboratory tests were done at the time of the TEAE and all laboratory assessments were within normal limits. The subject was treated with 25 mg of Promethazine, 2 mg of Benztropine, and 125 mg of Solumedrol, which resulted in the development of 2 additional TEAEs (somnolence and dry mouth), which are known side effects of the concomitant medications given. Somnolence

and dry mouth TEAEs were not considered related to study drug. Dystonia resolved the same day (04 June 2020), while somnolence resolved on day 4 (05 June 2020) and dry mouth on Day 5 (06 June 2020).

Subject 01S2079 (21-year-old male) was randomized and enrolled on 02 June 2020 and received 100 mg LB-102 BID in Cohort 7. This subject experienced nausea, vomiting, and an acute dystonic reaction on Day 3 (04 June 2020). All resolved on the same day (04 June 2020). The subject withdrew consent on Day 3 (04 June 2020) for a family emergency and did not agree to stay for at least a 24-hour post dose safety evaluation and left against the PI's medical advice. He did not have any symptoms of dystonia before he left the study center and had a normal physical exam at discharge. Safety labs and prolactin were done at discharge. After the subject went home, the subject experienced nausea and two bouts of emesis. The subject also developed acute dystonic reaction approximately 2 hours post morning dose and experienced symptoms of neck/generalized muscle spasms/tongue swelling. He went to the emergency room via ambulance for these symptoms. The subject was administered 50 mg intravenous Benadryl (Acrivastine) at 11:05, 4 mg of intravenous Zofran (Ondansetron), and about 1300 ml of 0.9% normal saline while in the emergency room and his symptoms improved. Chemistry and hematology laboratory tests were done in the emergency room and were within normal limits. The subject was followed up with by the PI and did not report any recurrence or additional new symptoms on Day 4 (05 June 2020) and Day 11 (12 June 2020).

Subject 01S2092 (32-year-old male) was randomized and enrolled on 23 June 2020 and received 75 mg LB-102 BID in Cohort 8. The subject experienced a migraine on Day 2 (24 June 2020) that worsened on Day 3 following administration of the morning dose. The migraine was possibly related to the study drug. The subject reported that the pain radiated down from his head to his neck and back. The migraine resolved on Day 3 following administration of 400 mg ibuprofen twice (Time 13:52 and 14:10). On Day 3 (25 June 2020), this subject experienced acute dystonic reaction after administration of the morning dose. The reaction was considered definitely related to LB-102. The dystonia was characterized by restlessness and muscle spasms mostly in the throat, neck, and upper back. This diagnosis was confirmed on an unscheduled physical examination. There were no other neurological deficits or abnormal psychological examinations noted for this subject. The subject was given IV administration of benztropine 2 mg at 19:50 and promethazine 25 mg at 19:53 and the dystonia resolved. Study drug administration was halted in response to the migraine and dystonic reaction. The subject voluntarily withdrew consent the next day (26 June 2020).

### **12.3.3 Analysis and Discussion of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events**

Not applicable.

## 12.4 Clinical Laboratory Evaluation

Statistical Tables 14.3.4.1.1 to 14.3.4.1.11 contain a summary of the chemistry laboratory data by cohort and study visit. Data Listing 16.2.8.1.1 contains the subject data listings for chemistry laboratory test results by visit. A majority of the clinically significant abnormal values were related to elevated prolactin. Prolactin levels increased in all subjects treated with at least one dose of LB-102 (N=48) and increased to clinically significant levels ( $\geq 100 \mu\text{g/L}$ ) in 11 subjects. In the Placebo group, 10 subjects (out of 16) had elevated prolactin levels on at least 1 visit, but no concentration reached a clinically significant level.

### 12.4.1 Prolactin Chemistry Laboratory Results

Normal prolactin levels for non-pregnant females is 4.9-23.2  $\mu\text{g/L}$  and for males is 4.1-15.1  $\mu\text{g/L}$ . Clinically significant levels resulting in AEs were considered to concentrations  $\geq 100 \mu\text{g/L}$ .

In subjects receiving 50 mg LB-102 QD (Cohort 1), all 6 subjects had high prolactin levels on Day 3 (24 January 2020). Two (2) of those subjects also had high prolactin on an unscheduled visit on 29 January 2020 (27.6  $\mu\text{g/L}$ , 01S0004, female and 22  $\mu\text{g/L}$ , 01S0008, male). Three (3) of the 6 subjects (01S0002, 01S0003, and 01S0004) had  $\geq 100 \mu\text{g/L}$  prolactin levels on Day 3, resulting in AEs of mild severity.

In subjects receiving 10 mg LB-102 QD (Cohort 2), all 6 subjects had increased prolactin levels on Day 3 (06 February 2020). Subject 01S0030 (female) had high prolactin at baseline (28.5  $\mu\text{g/L}$ ), but levels rose to clinically significant values on Day 3 (104.7  $\mu\text{g/L}$ ), resulting in an AE. Levels returned to normal on Day 8. Subject 01S0035 (male) continued to have slightly elevated prolactin relative to baseline on Day 8 (baseline= 7.3  $\mu\text{g/L}$ ; Day 1= 37.7  $\mu\text{g/L}$ ; Day 8= 18.1  $\mu\text{g/L}$ ). Prolactin levels in all other subjects returned to normal on Day 8.

In subjects receiving 100 mg LB-102 QD (Cohort 3), all 6 subjects had high prolactin levels on Day 3 (20 February 2020). Prolactin in only 1 subject (01S0063, female) rose to a clinically significant level (130.3  $\mu\text{g/L}$ ), resulting in an AE. Prolactin returned to normal on Day 8 (20.6  $\mu\text{g/L}$ ). Two (2) subjects (01S0073 and 01S0074, males) continued to have high prolactin levels on Day 8 (16.2  $\mu\text{g/L}$  and 27.4  $\mu\text{g/L}$ ). Prolactin levels in all other subjects returned to normal on Day 8.

In subjects receiving 200 mg LB-102 QD (Cohort 4), all 6 subjects had elevated prolactin levels on Days 3 (05 March 2020) and 8 (10 March 2020). None of the elevations were above 100  $\mu\text{g/L}$  and were therefore not considered AEs. Subjects 01S0104 (male) and 01S0109 (male) also had elevated prolactin on an unscheduled visit on 13 March 2020 (19.3  $\mu\text{g/L}$ ) and on 16 March 2020 (38  $\mu\text{g/L}$ ), respectively. Subject 01S0120 (female) continued to have elevated prolactin on unscheduled visits on 16 March 2020 (81.8  $\mu\text{g/L}$ ) and 27 March 2020 (25.1  $\mu\text{g/L}$ ).

In subjects receiving 150 mg LB-102 QD (Cohort 5), all 6 subjects had high prolactin levels on Day 3 (20 April 2020) and continued to be elevated on Days 8 (25 April 2020) and 15 (02 May 2020). Prolactin in only 1 subject (01S0157, female) rose to a clinically significant level on Days 3 and 8 (Day 3= 118  $\mu\text{g/L}$ ; Day 8= 223  $\mu\text{g/L}$ ), resulting in a mild AE. Their prolactin level was 40.6  $\mu\text{g/L}$  on Day 15.

In subjects receiving 50 mg LB-102 BID (Cohort 6), all 6 subjects had high prolactin levels on Day 4 (15 May 2020) and continued to be elevated on Days 9 (20 May 2020) and 15 (26 May 2020). Prolactin in 2 subjects (01S2050 and 01S2053, males) rose above 100 µg/L on Day 9 (01S2050= 100 µg/L; 01S2053= 148 µg/L), resulting in mild AEs. Both subjects were asymptomatic. The AEs were considered definitely related to LB-102 in Cohort 6. The AE resolved by Day 15 Follow-Up Visit.

In subjects receiving 100 mg LB-102 BID (Cohort 7), all 6 subjects had high prolactin on Day 4 (05 June 2020) and/or all unscheduled visits (04 June 2020 and 12 June 2020), if they had any. Prolactin in only one subject (01S2069, female) rose to a clinically significant level on an unscheduled visit on 04 June 2020 (170 µg/L) and remained high on an unscheduled visit on 12 June 2020 (96.7 µg/L), resulting in a mild AE.

One (1) mild, Grade 1 AE (elevated prolactin, > 100 ng/mL) was experienced by 1 subject on Day 3. The subject was asymptomatic. The AE was considered definitely related to LB-102 in Cohort 7. The AE resolved by Day 11 Follow-Up Visit.

Two (2) moderate, Grade 2 AEs (acute dystonic reaction) were experienced by 2 subjects on Day 3, 1 and 3 hours post dose, respectively. The acute dystonic reaction was definitely related to the study drug in Cohort 7. Both AEs resolved on the same day following treatment with concomitant medication for the symptoms. No recurrences were experienced by both subjects.

According to [Section 8.5.3](#) of the LB-102-001 Clinical Protocol (Version 5, 18 May 2020), this triggered a stopping criterion (two or more LB-102 or placebo- treated subjects experience a ≥ Grade 2 AE in the same system organ class that is not clearly unrelated to LB-102 or placebo) for Cohort 7. The Investigator and Sponsor agreed to immediately halt dosing for all subjects in Cohort 7 for the safety of the remaining subjects on 04 June 2020. In accordance with Section 8.5.3 of the Clinical Protocol, and based on the discussion of the PK and Safety Tolerability of the 100 mg (BID; 200 mg/day) dose of LB-102 (Cohort 7), the SRC voted for an intermediate dose of 75 mg BID (150 mg/day; lower than the Cohort 7 dose of 100 mg BID [200 mg/day]) for Cohort 8 ([LB-102-001 Cohort 7 SRC Meeting Minutes, 22Jun2020, Data Listing 16.2.1](#)).

In subjects receiving 75 mg LB-102 BID (Cohort 8), all 6 subjects had high prolactin levels on Days 4 (26 June 2020), 9 (01 July 2020), 15 (07 July 2020), any unscheduled visits (28 June 2020), and/or at early termination (26 June 2020). Prolactin in two subjects (01S2080 and 01S2094, females) rose above 100 µg/L resulting in AEs. Prolactin in subject 01S2080 was elevated on Day 4 (107 µg/L), Day 9 (209 µg/L), Day 15 (56.3 µg/L), and on an unscheduled visit on 28 June 2020 (172 µg/L). Prolactin in subject 01S2094 was elevated on Day 4 (146 µg/L), Day 9 (208 µg/L), Day 15 (93.5 µg/L), and on an unscheduled visit on 28 June 2020 (179 µg/L).

In the Placebo group, 10 out of the 16 subjects had high prolactin levels on at least one visit. The highest level reached was 42.8 µg/L on Day 3 (20 April 2020) in subject 01S0154 (male). No levels were considered clinically significant.

### 12.4.2 Other Chemistry Laboratory Results

The majority of the other chemistry laboratory results remained at or near normal levels, without a clinically significant change from baseline.

Creatinine levels remained largely unchanged from baseline. There were a number of subjects (N=7) who had high levels at baseline and continued to have high levels ( $\geq 1.00$  mg/dL in females,  $\geq 1.27$  mg/dL in males) throughout the study. One (1) subject (01S0169) had normal levels at baseline (1.23 mg/dL) but had increased levels on Day 8 (1.33 mg/dL). They had an AE for back pain. Creatinine levels were low ( $\leq 0.57$  mg/dL in females, 0.76 mg/dL in males) in 2 subjects (Placebo, N=2) on at least one visit, with the lowest value being 0.56 mg/dL in subject 01S0068 (male, Placebo) on Day 2. However, this subject also had low creatinine at baseline (0.52 mg/dL). Subject 01S0001 (male, Placebo) had low creatinine (0.75 mg/dL) on Day 8.

Alanine aminotransferase was high ( $\geq 32$  IU/L in females,  $\geq 44$  IU/L in males) in one subject 01S2055 (25-year-old male receiving 50 mg BID, Cohort 6) on Days 4 (56 IU/L), 8 (47 IU/L), and on an unscheduled visit on 16 May 2020 (56 IU/L). Values were normal at baseline and Days 0 and 15.

### 12.4.3 Hematology Laboratory Results

Summaries of hematology data for each cohort are located in [Statistical Tables 14.3.4.2.1 to 14.3.4.2.15](#). Subject data listings for hematology test results are found in [Data Listing 16.2.8.1.2](#). There were no clinically significant changes in hematology laboratory results during the study.

### 12.4.4 Urinalysis Laboratory Results

Summaries of urinalysis test results for each cohort are located in [Statistical Tables 14.3.4.3.1 to 14.3.4.3.10](#). Subject data listings for urinalysis test results are found in [Data Listing 16.2.8.1.3](#). There were no clinically significant changes in urinalysis laboratory results during the study. There were 3 cases of trace amounts of urinary ketones, 7 positive cases of leukocyte esterase, 1 positive case of nitrite, 3 cases of occult blood, and 1 case of urinary protein.

## 12.5 Vital Signs, Physical Findings, and Other Observations Related to Safety

### 12.5.1 Vital Signs

Summaries of vital signs on each visit and the change from pre-dose are located in [Statistical Table 14.3.5.1](#). Subject data listings for vital signs are found in [Data Listing 16.2.8.2](#). Blood pressure, heart rate, respiratory rate, and temperature were largely unchanged across the time points from pre-dose Day 1 in all cohorts.

Systolic blood pressure was mostly unaffected and ranged between 91-156 mmHg across all visits and cohorts. On average, there appears to be a slight decrease in blood pressure of a few mmHg across the cohorts at the later time points. For example, on Day 1, 8 hours post-dose, the change from pre-dose ranged between -12 mmHg in subjects taking 75 mg LB-102 BID (Cohort 8) to +2.7 mmHg in subjects taking 100 mg LB-102 QD (Cohort 3). All cohorts except Cohort 3 decreased systolic blood pressure 8 hours post-dose on Day 1. This trend continued on Days 2-15 in subjects taking LB-102 BID (cohorts 6-8). There were a few cases of increased systolic pressure from pre-dose, with the greatest increase being +41 mmHg 24 hours later in subject 01S0156



receiving 150 mg LB-102 QD (Day 1 pre-dose= 106 mmHg; Day 2, 24 hrs post-dose= 147 mmHg). Subject 01S0160 (150 mg LB-102 QD) had the maximum systolic blood pressure on Day 1, 0.5 hrs post LB-102 (pre-dose= 133 mmHg; post 0.5 hrs= 156 mmHg). Values at other time points for this subject ranged between 128 mmHg (2 hours post-dose) to 143 (12 hours post-dose) and there was not a clear increase in pressure across time points. Similarly, subject 01S0008 (50 mg LB-102 QD) had increased systolic blood pressure, peaking at 2 hours post-dose (pre-dose=130 mmHg; 2 hours post-dose=148 mmHg), but the ranges were generally variable across time points and screening pressure was also on the higher end at 139 mmHg.

Similar to systolic blood pressure, diastolic blood pressure was largely unchanged but on average had a slight decrease at later time points in all cohorts. Diastolic blood pressure ranged between 51-107 mmHg across all visits and cohorts. The largest drop in pressure from pre-dose was -26 mmHg in subject 01S0075 taking Placebo (Day 1 pre-dose=77 mmHg; post-4 hours=51 mmHg). The largest increase in diastolic pressure from pre-dose was +34 mmHg in subject 01S0157 taking 150 mg LB-102 QD (Cohort 5, Day 1 pre-dose= 61 mmHg; post 0.5 hr= 95 mmHg). Diastolic pressure continued to be elevated at all other time points post-dose (range= 80-91 mmHg) for this subject, but it is noted that pressure was 80 mmHg at Day 0 and 81 mmHg at the screening visit. Subject 01S0073 (Cohort 3) had the maximum diastolic blood pressure (107 mmHg) on Day 8. This subject had pressure between 60 mmHg to 87 mmHg at all other time points.

Pulse rate ranged between 46-116 beats/min across all visits and cohorts. There was no clear directional change in pulse rate across time points on Day 1. However, there appears to be an increase in pulse rate on Days 3-8. Note that the change from pre-dose is calculated from pre-dose on Day 1 and not the change from pre-dose on the same Day as the drug was dosed (for MAD subjects). The largest decrease from pre-dose was -37 beats/min in subject 01S0010 taking 50 mg LB-102 QD (Cohort 1, Day 1, pre-dose= 99 beats/min; Day 8= 62 beats/min). The greatest increase from pre-dose was 40 beats/min in subject 01S2080 taking 75 mg LB-102 BID (Cohort 8). In this subject, pulse rate was 76 beats/min at pre-dose on Day 1. On Day 5, pulse rate was 91 beats/min at pre-dose and increased to 116 beats/min post-dose. Since pulse rate from pre-dose on Day 1 was used to calculate the amount of change post-dose, this corresponded to a +40 beats/min change from pre-dose. This subject didn't have a consistent increase in pulse rate post-dose on the visits as some rates decreased post-dose.

Respiratory rate was mostly unaffected during treatment and the range across all subjects was 12-20 breaths/min. The maximum decrease in respiratory rate from pre-dose was -4 breaths/min and the maximum increase was +6 breaths/min.

Body temperature was largely unchanged during treatment and the range for all subjects was between 36.3-37.5 °C.

### 12.5.2 Physical Examination – Shift from Baseline

The physical examination shift from baseline results for each cohort are summarized and provided in [Statistical Table 14.3.5.3.2](#). Subject data listings for physical examinations are provided in [Data Listing 16.2.8.5](#). Physical examinations mostly remained unchanged during the treatment.

Eye exam: One (1) subject (01S2047) in the placebo group had a normal eye exam at baseline that shifted to abnormal on Day 4.

Musculoskeletal exam: One (1) subject (01S0169) in the placebo group had a normal musculoskeletal exam at baseline that shifted to abnormal on day 2 associated with a TEAE of back pain.

Ear exam: One (1) subject (01S2082) in the placebo group had a normal ear examination at baseline, but then had abnormal exams on each examination day except Day 4. One subject in the placebo group had a normal ear exam at baseline but had abnormal exams on all other visits.

Skin exam: One (1) subject (01S2095) in the placebo group had normal skin examination at baseline but had an abnormal exam on Day 8 associated with an arthropod bite TEAE.

Nose exam: One (1) subject (01S0071) taking 100 mg LB-102 QD (Cohort 3) had a normal examination at baseline that shifted to abnormal on Day 8 associated with a TEAE of an upper respiratory tract infection.

### 12.5.3 Electrocardiogram (ECG)

Summaries of ECG results at every visit for each cohort are located in [Statistical Table 14.3.5.2](#). Subject data listings for ECG results are found in [Data Listing 16.2.8.3](#).

No subject reached the QT prolongation stopping criteria of an increase in QTcF interval to >500 msec for male and female subjects or an increase in QTcF of >60 msec over baseline. However, there were several noteworthy findings. Subject 01S0116 (31-year-old female) receiving 200 mg LB-102 QD (Cohort 4) experienced an AE of increased QTcF prolongation (41 msec) at 2 hours post-dose that was definitely related to study drug (pre-dose= 417 msec; 2 hours post-dose= 458 msec). The QTcF prolongation resolved by 4 hours post-dose (437.9 msec) without any concomitant medications. See [Section 14.3.3](#) for the narrative. The rest of the 5 subjects (01S0103, 01S0104, 01S109, 01S0119, 01S0120) receiving 200 mg LB-102 QD (Cohort 4) had increased QTcF (20-46 msec) from pre-dose, but none were elevated >450 msec. The concern for QTcF prolongation at this dosage caused the SRC to reduce the dose in Cohort 5 to 150 mg LB-102 QD. There were 5 additional subjects (01S0042, 10 mg QD; 01S0063, 100 mg QD; 01S0156, 150 mg QD; 01S0165, 150 mg QD) with an increase in prolonged QTcF interval from pre-dose (40-46 msec), but none rose >450 msec.

PR interval remained largely unchanged. There were 2 subjects presenting with an interval >200 msec. Subject 01S0064 receiving 100 mg LB-102 QD (Cohort 3) had an elevated PR interval at 2 hours post-dose that returned below baseline by 4 hours (pre-dose= 191 msec; 2 hours post-dose= 203 msec; 4 hours post-dose= 186 msec). Subject 01S0099 (Placebo) had an elevated PR interval at 4 hours post-dose that returned to below baseline values by 6 hours (pre-dose= 193 msec; 4 hours post-dose= 201 msec; 6 hours post-dose= 189 msec).

Heart rates that were <40 and >100 beats/min were flagged as abnormal. ECG mean heart rate tended to increase slightly (about 2-6 beats/min) from pre-dose at the later time points (Day 1, 4 hours post-dose to Day 8) in all cohorts. One (1) subject (01S0073, 100 mg LB-102 QD, Cohort 3, male) had an abnormally low heart rate of 38 beats/min on Day 1, 2 hours post-dose and



on Day 2, 24 hours post-dose. Baseline pre-dose heart rate was 41 beats/min. This heart rate was considered not clinically significant because the subject was an avid runner ([Cohort 3 SRC Meeting Minutes](#), [Data Listing 16.2.1](#)).

QRS duration was largely unchanged post-dose and no subject had values above 120 msec. One (1) subject (01S0064, 100 mg LB-102 QD, Cohort 3, male) had a QRS duration of 119 msec at 4 hours post-dose. Note that pre-dose values were also high at 117 msec.

QT interval seemed to initially increase until 2 hours post-dose in all cohorts but started to decrease thereafter. Subject 01S0073 (male) taking 100 mg LB-102 QD (Cohort 3) reached a QT interval of 507 msec on Day 1, 2 hours post-dose and 501 msec on Day 2, 24 hours post-dose. These values were elevated from their pre-dose value of 481 msec. After SRC review, this was not considered clinically significant. No other subject had a QT interval >500 msec. Eight (8) subjects taking LB-102 (50 mg QD, N=1; 200 mg QD, N=1; 150 mg QD, N=2; 100 mg BID, N=3; 75 mg BID, N=1) had elevated QT interval >440 msec, but less than the clinically significant threshold 500 msec.

#### 12.5.4 Columbia-Suicide Severity Rating Scale (C-SSRS)

The C-SSRS questionnaire results for each cohort are located in [Statistical Table 14.3.5.5](#). Subject data listings for C-SSRS results are found in [Data Listing 16.2.8.4](#). All subjects answered no at every visit to all questions on the C-SSRS questionnaire.

### 12.6 Safety Conclusions

LB-102 was generally well-tolerated with all TEAEs either mild (37) or moderate (6) severity. Out of the 64 subjects, 28 subjects (50 mg QD, N=4; 10 mg QD, N=2; 100 mg QD, N=3; 200 mg QD, N=3; 150 mg QD, N=1; 50 mg BID, N=2; 100 mg BID, N=3; 75 mg BID, N=5; Placebo, N=5) experienced at least one TEAE, with a total of 43 TEAEs. Out of the 43 TEAEs, 29 (50 mg QD, 3; 10 mg QD, 1; 100 mg QD, 3; 200 mg QD, 5; 150 mg QD, 1; 50 mg BID, 2; 100 mg BID, 5; 75 mg BID, 8; Placebo, 1) were considered possibly, probably, or definitely related to treatment.

Of the TEAEs definitely related to study drug, there were 11 cases of elevated prolactin ( $\geq 100$   $\mu\text{g/L}$ ; 50 mg QD, N=3; 10 mg QD, N=1; 100 mg QD, N=1; 150 mg QD, N=1; 50 mg BID, N=2; 100 mg BID, N=1; 75 mg BID, N=2), 4 cases of moderate dystonia (200 mg QD, N=1; 100 mg BID, N=2; 75 mg BID, N=1), and 1 case of mild ECG QTcF prolongation (458 msec, 200 mg LB-102 QD) that were all resolved with either no course of action (prolactin increase and QTcF interval prolongation) or concomitant medications (dystonia). Due to 2 TEAEs in the same system organ class (acute dystonic reaction), treatment was halted in all subjects taking 100 mg LB-102 BID (Cohort 7) and the 2 subjects in Cohort 7 taking placebo. As a result, the SRC concluded to reduce the dose for Cohort 8 to 75 mg LB-102 BID. Additionally, because QTcF interval was fairly prolonged from pre-dose values (20-46 msec) in all subjects taking 200 mg LB-102 QD (Cohort 4), the dosage for Cohort 5 was reduced to 150 mg LB-102 QD. Of the TEAEs probably or possibly related to study drug, there were 4 cases of nausea (100 mg LB-102 QD, N=1; 200 mg LB-102, N=1; 100 mg LB-102 BID, N=1; 75 mg LB-102 BID, N=1) and 1 case of vomiting (100 mg LB-102 BID), urticaria (100 mg LB-102 QD), gastroesophageal disease (200 mg LB-102), insomnia (75 mg LB-102 BID), dizziness (75 mg LB-102 BID), and somnolence (75 mg LB-102 BID).

Vital signs and physical examination results were largely unchanged from baseline. Other than mild increases in prolactin, chemistry laboratory results were also largely unchanged throughout study treatment. C-SSRS did not change during study treatment.

### 13. DISCUSSION AND OVERALL CONCLUSIONS

LB-102 is a dopaminergic D<sub>2</sub> and D<sub>3</sub> receptor antagonist indicated for the treatment of patients with schizophrenia. LB-102-001 was a randomized, double-blinded, placebo-controlled Phase 1 study to evaluate the safety and the tolerability of a single oral dose and multiple oral doses of LB-102 compared to placebo in healthy subjects.

This Phase 1 study included 64 healthy subjects with 8 subjects (6 LB-102, 2 placebo) in 8 cohorts. In Part A (SAD), Cohort 1 received a 50 mg LB-102 QD, Cohort 2 received 10 mg LB-102 QD, Cohort 3 received 100 mg LB-102 QD, Cohort 4 received 200 mg LB-102 QD, and Cohort 5 received 150 mg LB-102 for one day (Day 1). In Part B (MAD), Cohort 6 received 50 mg LB-102 BID, Cohort 7 received 100 mg LB-102 BID, and Cohort 8 received 75 mg LB-102 BID for 6 days and QD on Day 7. All subjects in receiving study drug in Part A (Cohorts 1-5) completed the study. All 6 subjects receiving 100 mg LB-102 BID (Cohort 7), the 2 subjects taking placebo in Cohort 7, and 1 subject receiving 75 mg LB-102 BID (Cohort 8), did not complete the treatment course. Study treatment was halted for subjects taking 100 mg LB-102 BID due to a stopping criterion being met.

LB-102 was generally well-tolerated with all TEAEs either mild (37) or moderate (6) severity. Out of the 64 subjects, 28 subjects experienced at least one TEAE, with a total of 43 TEAEs. Out of the 43 TEAEs, 29 were considered possibly, probably, or definitely related to treatment.

All subjects receiving LB-102 experienced elevated prolactin levels, but only 11 cases (50 mg QD, N=3; 10 mg QD, N=1; 100 mg QD, N=1; 150 mg QD, N=1; 50 mg BID, N=2; 100 mg BID, N=1; 75 mg BID, N=2) were elevated to clinically significant levels ( $\geq 100$   $\mu\text{g/L}$ ) and were considered TEAEs definitely related to study drug.

Additionally, there were 4 cases of moderate dystonia (200 mg QD, N=1; 100 mg BID, N=2; 75 mg BID, N=1) and 1 case of mild ECG QTcF prolongation (458 msec, 200 mg LB-102 QD), which were TEAEs definitely related to study drug. All TEAEs were resolved. However, the 2 TEAEs of dystonic reaction in subjects taking 100 mg LB-102 BID led to treatment discontinuation in Cohort 7 and a reduction in the drug dose to 75 mg LB-102 BID in Cohort 8. Additionally, because QTcF interval was fairly prolonged from pre-dose values (20-46 msec) in all subjects taking 200 mg LB-102 QD (Cohort 4), the dosage for Cohort 5 was reduced to 150 mg LB-102 QD. Of the TEAEs probably or possibly related to study drug, there were 4 cases of nausea and 1 case of vomiting, urticaria, gastroesophageal disease, insomnia, dizziness, and somnolence.

Vital signs and physical examination results were largely unchanged from baseline. Other than increases in prolactin, chemistry laboratory results were also relatively unchanged throughout study treatment. C-SSRS did not change during study treatment.

The PK results in Part A (SAD) revealed that LB-102 was rapidly absorbed and LB-102 concentration generally declined from peak in an apparent biphasic manner. Exposure increased in a slightly greater than dose-proportional manner. Apparent clearance appeared to decrease as dose increased. Amisulpride was formed quickly over time after a single dose of LB-102 and generally declined with an approximate biphasic disposition of comparable shape to LB-102 but at approximately 2.5% of LB-102 abundance. The plasma concentrations of amisulpride at lower doses were within several fold of LLOQ making descriptive PK analysis tenuous. In fact, amisulpride was not detected in subjects taking 10 mg LB-102 QD (Cohort 2). In vitro studies suggest equal pharmacological potency between LB-102 and amisulpride, but since amisulpride is present at 2.5% LB-102 concentration, it thus represents a minor active metabolite (defined as either less than 10% parent concentration or less than 10% of total pharmacological activity).

The PK results in Part B (MAD) revealed that trough concentrations of LB-102 and amisulpride plateaued before the morning dose on Day 4. After multiple doses, there was slight to moderate accumulation of LB-102 across dose levels. Amisulpride had a higher accumulation than LB-102 across dose levels. Exposure to LB-102 increased in a dose proportional manner. Apparent clearance at steady state to LB-102 appeared to be similar as dose increased.

LB-102 was designed to be an improved version of the amisulpride by having increased permeability across the blood-brain-barrier, which would potentially decrease the plasma concentrations needed to achieve efficacy. This would thereby decrease the magnitude and frequency of AEs typically observed in schizophrenia patients treated with amisulpride. The maximum tolerated dose of LB-102 was identified as 150 mg per day as either 150 mg QD or 75 mg BID. LB-102-001 achieved its objectives of identifying the safety, tolerability, and PK of a single oral dose and multiple oral doses of LB-102 in healthy subjects.

## **14. TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT**

### **14.1 Demographic Data Summary Figures and Tables**

<b>Number</b>	<b>Title</b>
<a href="#">14.1.1</a>	Disposition of Subjects (All screened subjects)
<a href="#">14.1.2</a>	Demographics and Baseline Characteristics (Safety Population)
<a href="#">14.1.3</a>	Medical History (Safety Population)
<a href="#">14.1.4</a>	Treatment Compliance (Safety Population)

### **14.2 Pharmacokinetics Data Summary Figures and Tables**

[LB-102 PK Report](#) (Appendix 16.1.9).

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Table 14.1.1 - Disposition of Subjects

		Treatment Group*				
		Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
Total number of screened:	288					
Screened failure:	224					
Randomized		6	6	6	6	6
Treated		6	6	6	6	6
Completed the Study	N	6	6	6	6	6
	Yes	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Primary Reason for Discontinuation						
	Adverse Event	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Protocol Deviation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.1 - Disposition of Subjects

		Treatment Group*				
		Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
Primary Reason for Discontinuation	Withdrawal by Subject	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Lost to Follow-Up	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Investigator Recommendation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Other	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.1 - Disposition of Subjects

		Treatment Group*			
		Cohort 6	Cohort 7	Cohort 8	Placebo
Total number of screened:	288				
Screened failure:	224				
Randomized		6	6	6	16
Treated		6	6	6	16
Completed the Study	N	6	6	6	16
	Yes	6 (100.0%)	0 ( 0.0%)	5 ( 83.3%)	14 ( 87.5%)
	No	0 ( 0.0%)	6 (100.0%)	1 ( 16.7%)	2 ( 12.5%)
Primary Reason for Discontinuation					
	Adverse Event	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Protocol Deviation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.1 - Disposition of Subjects

		Treatment Group*			
		Cohort 6	Cohort 7	Cohort 8	Placebo
Primary Reason for Discontinuation	Withdrawal by Subject	0 ( 0.0%)	3 ( 50.0%)	1 ( 16.7%)	0 ( 0.0%)
	Lost to Follow-Up	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Investigator Recommendation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Other	0 ( 0.0%)	3 ( 50.0%)	0 ( 0.0%)	2 ( 12.5%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Age (years)	N	6	6	6	6	6
	Mean	37.2	31.3	35.0	28.8	31.0
	SD	8.2	10.7	9.8	11.7	11.5
	Median	38.5	27.5	31.5	25.5	29.0
	Minimum	22	21	26	18	19
	Maximum	45	47	54	45	44
Gender	N	6	6	6	6	6
	Male	2 ( 33.3%)	4 ( 66.7%)	4 ( 66.7%)	4 ( 66.7%)	4 ( 66.7%)
	Female	4 ( 66.7%)	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Age (years)	N	6	6	6	16
	Mean	31.7	34.8	44.0	40.1
	SD	4.9	9.8	8.7	12.3
	Median	32.5	35.5	44.5	43.0
	Minimum	23	21	32	20
	Maximum	37	48	53	55
Gender	N	6	6	6	16
	Male	6 (100.0%)	5 ( 83.3%)	4 ( 66.7%)	12 ( 75.0%)
	Female	0 ( 0.0%)	1 ( 16.7%)	2 ( 33.3%)	4 ( 25.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Race	N	6	6	6	6	6
	American Indian or Alaska Native	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Asian	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Black or African American	2 ( 33.3%)	3 ( 50.0%)	4 ( 66.7%)	6 (100.0%)	5 ( 83.3%)
	Native Hawaiian or other Pacific Islander	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	White	3 ( 50.0%)	3 ( 50.0%)	2 ( 33.3%)	0 ( 0.0%)	1 ( 16.7%)
	Multiple	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Height (cm)	N	6	6	6	6	6
	Mean	166.8	168.5	183.0	171.7	174.9
	SD	7.5	8.8	10.0	7.3	6.6
	Median	166.6	169.4	188.5	169.1	175.8
	Minimum	159	157	168	164	163

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Height (cm)	Maximum	180	178	191	182	182

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Race	N	6	6	6	16
	American Indian or Alaska Native	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Asian	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Black or African American	4 ( 66.7%)	5 ( 83.3%)	2 ( 33.3%)	9 ( 56.3%)
	Native Hawaiian or other Pacific Islander	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	White	2 ( 33.3%)	1 ( 16.7%)	4 ( 66.7%)	7 ( 43.8%)
	Multiple	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Height (cm)	N	6	6	6	16
	Mean	174.5	175.2	170.6	172.6
	SD	3.3	7.8	11.0	9.5
	Median	175.0	173.1	173.3	173.7
	Minimum	169	168	157	154

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Height (cm)	Maximum	178	190	182	187

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Weight (kg)	N	6	6	6	6	6
	Mean	72.1	68.7	85.0	71.2	74.5
	SD	13.5	15.7	18.0	6.4	7.8
	Median	70.8	66.0	80.5	71.0	74.2
	Minimum	57	51	61	64	63
	Maximum	97	87	107	81	85
BMI (kg/m <sup>2</sup> )	N	6	6	6	6	6
	Mean	25.7	23.9	25.3	24.2	24.3
	SD	3.2	3.1	4.2	3.3	2.1
	Median	26.1	23.6	25.0	24.3	24.4
	Minimum	20	21	21	20	21
	Maximum	30	28	30	28	27

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.2 - Demographics and Baseline Characteristics

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Weight (kg)	N	6	6	6	16
	Mean	79.4	69.9	70.1	75.3
	SD	8.6	6.8	8.4	11.2
	Median	80.1	71.3	71.9	76.8
	Minimum	66	60	59	52
	Maximum	91	79	82	93
BMI (kg/m <sup>2</sup> )	N	6	6	6	16
	Mean	26.0	22.8	24.1	25.1
	SD	2.5	3.1	2.0	2.4
	Median	26.1	22.9	23.4	24.5
	Minimum	23	19	22	22
	Maximum	30	27	28	30

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.1.2.demog.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS					
ANAEMIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS					
HYDROCELE	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
PULMONARY MALFORMATION	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
EYE DISORDERS					
MYOPIA	0 ( 0.0%)	0 ( 0.0%)	4 (66.7%)	0 ( 0.0%)	1 (16.7%)
GASTROINTESTINAL DISORDERS					
INGUINAL HERNIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)
TOOTH IMPACTED	4 (66.7%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	4 (66.7%)
UMBILICAL HERNIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.1.3.mh.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
BLOOD AND LYMPHATIC SYSTEM DISORDERS				
ANAEMIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS				
HYDROCELE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PULMONARY MALFORMATION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
EYE DISORDERS				
MYOPIA	2 (33.3%)	0 ( 0.0%)	1 (16.7%)	3 (18.8%)
GASTROINTESTINAL DISORDERS				
INGUINAL HERNIA	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	1 ( 6.3%)
TOOTH IMPACTED	1 (16.7%)	2 (33.3%)	1 (16.7%)	3 (18.8%)
UMBILICAL HERNIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.1.3.mh.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
<b>IMMUNE SYSTEM DISORDERS</b>					
ALLERGY TO ANIMAL	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
FOOD ALLERGY	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
MYCOTIC ALLERGY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)
SEASONAL ALLERGY	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
<b>INFECTIONS AND INFESTATIONS</b>					
APPENDICITIS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
TONSILLITIS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
<b>INJURY, POISONING AND PROCEDURAL COMPLICATIONS</b>					
ANKLE FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
CLAVICLE FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
<b>IMMUNE SYSTEM DISORDERS</b>				
ALLERGY TO ANIMAL	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
FOOD ALLERGY	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
MYCOTIC ALLERGY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SEASONAL ALLERGY	0 ( 0.0%)	2 (33.3%)	0 ( 0.0%)	0 ( 0.0%)
<b>INFECTIONS AND INFESTATIONS</b>				
APPENDICITIS	0 ( 0.0%)	2 (33.3%)	0 ( 0.0%)	1 ( 6.3%)
TONSILLITIS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
<b>INJURY, POISONING AND PROCEDURAL COMPLICATIONS</b>				
ANKLE FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
CLAVICLE FRACTURE	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
FEMUR FRACTURE	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
GUN SHOT WOUND	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
LIGAMENT INJURY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
LIGAMENT RUPTURE	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SUPERFICIAL INJURY OF EYE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
WRIST FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)
INVESTIGATIONS					
CARDIAC MURMUR	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
LAPAROSCOPY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
BACK PAIN	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
FEMUR FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
GUN SHOT WOUND	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
LIGAMENT INJURY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
LIGAMENT RUPTURE	1 (16.7%)	1 (16.7%)	0 ( 0.0%)	1 ( 6.3%)
SUPERFICIAL INJURY OF EYE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
WRIST FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS				
CARDIAC MURMUR	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
LAPAROSCOPY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
BACK PAIN	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
ROTATOR CUFF SYNDROME	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SCOLIOSIS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SYNOVIAL CYST	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
TIBIA FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)					
UTERINE LEIOMYOMA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)
NERVOUS SYSTEM DISORDERS					
HEADACHE	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS					
ABORTION SPONTANEOUS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
RENAL AND URINARY DISORDERS					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
ROTATOR CUFF SYNDROME	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
SCOLIOSIS	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SYNOVIAL CYST	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
TIBIA FRACTURE	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)				
UTERINE LEIOMYOMA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
NERVOUS SYSTEM DISORDERS				
HEADACHE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS				
ABORTION SPONTANEOUS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.1.3.mh.sas



LB Pharmaceuticals, Inc.  
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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)

RENAL AND URINARY DISORDERS

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
NEPHROLITHIASIS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS					
DYSMENORRHOEA	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
TESTICULAR TORSION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
UTERINE PROLAPSE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					
ADENOIDAL DISORDER	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ASTHMA EXERCISE INDUCED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
ECZEMA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)
URTICARIA	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	1 (16.7%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
NEPHROLITHIASIS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS				
DYSMENORRHOEA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (12.5%)
TESTICULAR TORSION	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
UTERINE PROLAPSE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS				
ADENOIDAL DISORDER	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ASTHMA EXERCISE INDUCED	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
ECZEMA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
URTICARIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
SURGICAL AND MEDICAL PROCEDURES					
ADENOIDECTOMY	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
APPENDICECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
BAKER'S CYST EXCISION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
CAESAREAN SECTION	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
EXPLORATIVE LAPAROTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
EYELID OPERATION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
FEMALE STERILISATION	3 (50.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
FRACTURE TREATMENT	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
HYDROCELE OPERATION	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
HYSTERECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.1.3.mh.sas

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Protocol: LB-102-001

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
<b>SURGICAL AND MEDICAL PROCEDURES</b>				
ADENOIDECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
APPENDICECTOMY	0 ( 0.0%)	2 (33.3%)	0 ( 0.0%)	1 ( 6.3%)
BAKER'S CYST EXCISION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
CAESAREAN SECTION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
EXPLORATIVE LAPAROTOMY	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
EYELID OPERATION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
FEMALE STERILISATION	0 ( 0.0%)	0 ( 0.0%)	2 (33.3%)	3 (18.8%)
FRACTURE TREATMENT	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
HYDROCELE OPERATION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
HYSTERECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
INGUINAL HERNIA REPAIR	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)
KERATOMILEUSIS	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
LIGAMENT OPERATION	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
MAMMOPLASTY	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
OPEN REDUCTION OF FRACTURE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ORCHIDOPEXY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ROTATOR CUFF REPAIR	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SPINAL FUSION SURGERY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
THORACOTOMY	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
TONSILLECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
UMBILICAL HERNIA REPAIR	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
INGUINAL HERNIA REPAIR	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	1 ( 6.3%)
KERATOMILEUSIS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
LIGAMENT OPERATION	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 ( 6.3%)
MAMMOPLASTY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
OPEN REDUCTION OF FRACTURE	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ORCHIDOPEXY	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
ROTATOR CUFF REPAIR	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
SPINAL FUSION SURGERY	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
THORACOTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
TONSILLECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
UMBILICAL HERNIA REPAIR	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
VASECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
WISDOM TEETH REMOVAL	4 (66.7%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	4 (66.7%)
WRIST SURGERY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.1.3 - Medical History

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
VASECTOMY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
WISDOM TEETH REMOVAL	1 (16.7%)	2 (33.3%)	1 (16.7%)	3 (18.8%)
WRIST SURGERY	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.1.3.mh.sas

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Table 14.1.4 - Treatment Compliance

Complete Treatment Compliance	Treatment Group*								
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
N	6	6	6	6	6	6	6	6	16
Yes	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	0 ( 0.0%)	5 ( 83.3%)	14 ( 87.5%)
No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 (100.0%)	1 ( 16.7%)	2 ( 12.5%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day)

Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day)

Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

Program: 14.1.4.tc.sas

### 14.3 Safety Data Summary Figures and Tables

#### 14.3.1 Displays of Adverse Events

Number	Title
14.3.1.1	Number of Subjects with Treatment-Emergent Adverse Events (TEAE)
14.3.1.2	Number of Treatment-Emergent Adverse Events (TEAE)
14.3.1.3	Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term
14.3.1.4	Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity
14.3.1.5	Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Relationship to Study Drug
14.3.1.6	Adverse Events Leading to Discontinuation

#### 14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

Not Applicable.

#### 14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Not applicable.

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Table 14.3.1.1 - Number of Subjects with Treatment-Emergent Adverse Events (TEAE)

		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
At Least One Adverse Event	N	6	6	6	6	6
	Yes	4 ( 66.7%)	2 ( 33.3%)	3 ( 50.0%)	3 ( 50.0%)	1 ( 16.7%)
	No	2 ( 33.3%)	4 ( 66.7%)	3 ( 50.0%)	3 ( 50.0%)	5 ( 83.3%)
At Least One Mild or Moderate Adverse Event	N	4	2	3	3	1
	Yes	4 (100.0%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	1 (100.0%)
	No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
At Least One Severe Adverse Event	N	4	2	3	3	1
	Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	No	4 (100.0%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	1 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.1.1.ae\_p.sas

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Table 14.3.1.1 - Number of Subjects with Treatment-Emergent Adverse Events (TEAE)

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
At Least One Adverse Event	N	6	6	6	16
	Yes	2 ( 33.3%)	3 ( 50.0%)	5 ( 83.3%)	5 ( 31.3%)
	No	4 ( 66.7%)	3 ( 50.0%)	1 ( 16.7%)	11 ( 68.8%)
At Least One Mild or Moderate Adverse Event	N	2	3	5	5
	Yes	2 (100.0%)	3 (100.0%)	5 (100.0%)	5 (100.0%)
	No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
At Least One Severe Adverse Event	N	2	3	5	5
	Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	No	2 (100.0%)	3 (100.0%)	5 (100.0%)	5 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.1 - Number of Subjects with Treatment-Emergent Adverse Events (TEAE)

		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
At Least One Serious Adverse Event	N	4	2	3	3	1
	Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	No	4 (100.0%)	2 (100.0%)	3 (100.0%)	3 (100.0%)	1 (100.0%)
At Least One Not Related or Unlikely Related Adverse Event	N	4	2	3	3	1
	Yes	2 ( 50.0%)	1 ( 50.0%)	1 ( 33.3%)	2 ( 66.7%)	0 ( 0.0%)
	No	2 ( 50.0%)	1 ( 50.0%)	2 ( 66.7%)	1 ( 33.3%)	1 (100.0%)
At Least One Possibly or Probably or Definitely Related Adverse Event	N	4	2	3	3	1
	Yes	3 ( 75.0%)	1 ( 50.0%)	2 ( 66.7%)	3 (100.0%)	1 (100.0%)
	No	1 ( 25.0%)	1 ( 50.0%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.1 - Number of Subjects with Treatment-Emergent Adverse Events (TEAE)

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
At Least One Serious Adverse Event	N	2	3	5	5
	Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	No	2 (100.0%)	3 (100.0%)	5 (100.0%)	5 (100.0%)
At Least One Not Related or Unlikely Related Adverse Event	N	2	3	5	5
	Yes	0 ( 0.0%)	1 ( 33.3%)	1 ( 20.0%)	4 ( 80.0%)
	No	2 (100.0%)	2 ( 66.7%)	4 ( 80.0%)	1 ( 20.0%)
At Least One Possibly or Probably or Definitely Related Adverse Event	N	2	3	5	5
	Yes	2 (100.0%)	3 (100.0%)	5 (100.0%)	1 ( 20.0%)
	No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 ( 80.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.2 - Number of Treatment-Emergent Adverse Events (TEAE)

	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Adverse Event	5	2	4	8	1
Mild or Moderate Adverse Event	5	2	4	8	1
Severe Adverse Event	0	0	0	0	0
Serious Adverse Event	0	0	0	0	0
Not Related or Unlikely Related Adverse Event	2	1	1	3	0
Possibly or Probably or Definitely Related Adverse Event	3	1	3	5	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.2 - Number of Treatment-Emergent Adverse Events (TEAE)

	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Adverse Event	2	7	9	5
Mild or Moderate Adverse Event	2	7	9	5
Severe Adverse Event	0	0	0	0
Serious Adverse Event	0	0	0	0
Not Related or Unlikely Related Adverse Event	0	2	1	4
Possibly or Probably or Definitely Related Adverse Event	2	5	8	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
CARDIAC DISORDERS					
PALPITATIONS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
GASTROINTESTINAL DISORDERS					
ABDOMINAL PAIN	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
DIARRHOEA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
DRY MOUTH	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
GASTROESOPHAGEAL REFLUX DISEASE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
NAUSEA	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)
VOMITING	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
CARDIAC DISORDERS				
PALPITATIONS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
GASTROINTESTINAL DISORDERS				
ABDOMINAL PAIN	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
DIARRHOEA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
DRY MOUTH	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
GASTROESOPHAGEAL REFLUX DISEASE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
NAUSEA	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)
VOMITING	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
INFECTIONS AND INFESTATIONS					
UPPER RESPIRATORY TRACT INFECTION	1 ( 16.7%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
ARTHROPOD BITE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS					
BLOOD PROLACTIN INCREASED	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	1 ( 16.7%)
ELECTROCARDIOGRAM QT PROLONGED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
BACK PAIN	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
INFECTIONS AND INFESTATIONS				
UPPER RESPIRATORY TRACT INFECTION	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS				
ARTHROPOD BITE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
INVESTIGATIONS				
BLOOD PROLACTIN INCREASED	2 ( 33.3%)	1 ( 16.7%)	2 ( 33.3%)	0 ( 0.0%)
ELECTROCARDIOGRAM QT PROLONGED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
BACK PAIN	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	1 ( 6.3%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
NERVOUS SYSTEM DISORDERS					
DIZZINESS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
DYSTONIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
HEADACHE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
MIGRAINE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SOMNOLENCE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PSYCHIATRIC DISORDERS					
INSOMNIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
NERVOUS SYSTEM DISORDERS				
DIZZINESS	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	1 ( 6.3%)
DYSTONIA	0 ( 0.0%)	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)
HEADACHE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
MIGRAINE	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
SOMNOLENCE	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)
PSYCHIATRIC DISORDERS				
INSOMNIA	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS				

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
OROPHARYNGEAL PAIN	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
URTICARIA	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.3 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term

SYSTEM ORGAN CLASS / PREFERRED TERM	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
OROPHARYNGEAL PAIN	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS				
URTICARIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 1 LB-102 50 mg QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
GASTROINTESTINAL DISORDERS			
DIARRHOEA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INFECTIONS AND INFESTATIONS			
UPPER RESPIRATORY TRACT INFECTION	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS			
BLOOD PROLACTIN INCREASED	3 ( 50.0%)	0 ( 0.0%)	0 ( 0.0%)

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 2 LB-102 10 mg QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
GASTROINTESTINAL DISORDERS			
ABDOMINAL PAIN	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS			
BLOOD PROLACTIN INCREASED	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Protocol: LB-102-001

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 3 LB-102 100 mg QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
GASTROINTESTINAL DISORDERS			
NAUSEA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INFECTIONS AND INFESTATIONS			
UPPER RESPIRATORY TRACT INFECTION	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS			
BLOOD PROLACTIN INCREASED	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
URTICARIA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Protocol: LB-102-001

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 4 LB-102 200 mg QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
CARDIAC DISORDERS			
PALPITATIONS	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
GASTROINTESTINAL DISORDERS			
GASTROESOPHAGEAL REFLUX DISEASE	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
NAUSEA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS			
ELECTROCARDIOGRAM QT PROLONGED	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
NERVOUS SYSTEM DISORDERS			
DYSTONIA	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
HEADACHE	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
PSYCHIATRIC DISORDERS			
INSOMNIA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			
OROPHARYNGEAL PAIN	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 5 LB-102 150 mg QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
INVESTIGATIONS			
BLOOD PROLACTIN INCREASED	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Protocol: LB-102-001

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 6 LB-102 50 mg BID (6 days) + QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
INVESTIGATIONS			
BLOOD PROLACTIN INCREASED	2 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 7 LB-102 100 mg BID (6 days) + QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
<b>GASTROINTESTINAL DISORDERS</b>			
DRY MOUTH	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
NAUSEA	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
VOMITING	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
<b>INVESTIGATIONS</b>			
BLOOD PROLACTIN INCREASED	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
<b>NERVOUS SYSTEM DISORDERS</b>			
DYSTONIA	0 ( 0.0%)	2 ( 33.3%)	0 ( 0.0%)
SOMNOLENCE	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Protocol: LB-102-001

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Cohort 8 LB-102 75 mg BID (6 days) + QD (1 day)  
Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
GASTROINTESTINAL DISORDERS			
NAUSEA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS			
BLOOD PROLACTIN INCREASED	2 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
BACK PAIN	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
NERVOUS SYSTEM DISORDERS			
DIZZINESS	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
DYSTONIA	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
MIGRAINE	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
SOMNOLENCE	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
PSYCHIATRIC DISORDERS			
INSOMNIA	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Protocol: LB-102-001

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Table 14.3.1.4 - Number of Subjects with TEAE by MedDRA System Organ Class / Preferred Term and Severity

Treatment: Placebo (all cohorts combined)  
Number of Subjects: 16

SYSTEM ORGAN CLASS / PREFERRED TERM	Severity_N (%)		
	Mild	Moderate	Severe
GASTROINTESTINAL DISORDERS			
ABDOMINAL PAIN	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			
ARTHROPOD BITE	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
BACK PAIN	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)
NERVOUS SYSTEM DISORDERS			
DIZZINESS	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)
HEADACHE	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)

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Protocol: LB-102-001

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 1 LB-102 50 mg QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
GASTROINTESTINAL DISORDERS					
DIARRHOEA	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INFECTIONS AND INFESTATIONS					
UPPER RESPIRATORY TRACT INFECTION	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS					
BLOOD PROLACTIN INCREASED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 50.0%)

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Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 2 LB-102 10 mg QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
GASTROINTESTINAL DISORDERS					
ABDOMINAL PAIN	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS					
BLOOD PROLACTIN INCREASED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)

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Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 3 LB-102 100 mg QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
GASTROINTESTINAL DISORDERS					
NAUSEA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
INFECTIONS AND INFESTATIONS					
UPPER RESPIRATORY TRACT INFECTION	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS					
BLOOD PROLACTIN INCREASED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS					
URTICARIA	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 4 LB-102 200 mg QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
CARDIAC DISORDERS					
PALPITATIONS	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
GASTROINTESTINAL DISORDERS					
GASTROESOPHAGEAL REFLUX DISEASE	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
NAUSEA	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS					
ELECTROCARDIOGRAM QT PROLONGED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
NERVOUS SYSTEM DISORDERS					
DYSTONIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
HEADACHE	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PSYCHIATRIC DISORDERS					
INSOMNIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS					

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 4 LB-102 200 mg QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
OROPHARYNGEAL PAIN	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 5 LB-102 150 mg QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
INVESTIGATIONS					
BLOOD PROLACTIN INCREASED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 6 LB-102 50 mg BID (6 days) + QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
INVESTIGATIONS					
BLOOD PROLACTIN INCREASED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 7 LB-102 100 mg BID (6 days) + QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
GASTROINTESTINAL DISORDERS					
DRY MOUTH	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
NAUSEA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
VOMITING	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
INVESTIGATIONS					
BLOOD PROLACTIN INCREASED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
NERVOUS SYSTEM DISORDERS					
DYSTONIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)
SOMNOLENCE	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Cohort 8 LB-102 75 mg BID (6 days) + QD (1 day)

Number of Subjects: 6

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
<b>GASTROINTESTINAL DISORDERS</b>					
NAUSEA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
<b>INVESTIGATIONS</b>					
BLOOD PROLACTIN INCREASED	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 33.3%)
<b>MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS</b>					
BACK PAIN	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
<b>NERVOUS SYSTEM DISORDERS</b>					
DIZZINESS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
DYSTONIA	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
MIGRAINE	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
SOMNOLENCE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
<b>PSYCHIATRIC DISORDERS</b>					
INSOMNIA	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)

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Table 14.3.1.5-Number of Subjects with TEAE by MedDRA System Organ Class/Preferred Term and Relationship to Study Drug

Treatment: Placebo (all cohorts combined)

Number of Subjects: 16

SYSTEM ORGAN CLASS / PREFERRED TERM	Relationship to Study Drug_N (%)				
	Unrelated	Unlikely Related	Possibly Related	Probably Related	Definitely Related
GASTROINTESTINAL DISORDERS					
ABDOMINAL PAIN	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS					
ARTHROPOD BITE	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS					
BACK PAIN	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
NERVOUS SYSTEM DISORDERS					
DIZZINESS	1 ( 6.3%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
HEADACHE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)	0 ( 0.0%)

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Table 14.3.1.6 - Adverse Events Leading to Discontinuation

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There is no subject had adverse event leading to study discontinuation.

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#### 14.3.4 Abnormal Laboratory Value Listing

Number	Title
14.3.4.1.1	Laboratory Test Results – Chemistry: Albumin
14.3.4.1.2	Laboratory Test Results – Chemistry: Alkaline Phosphatase (ALP)
14.3.4.1.3	Laboratory Test Results – Chemistry: Aminotransferase (ALT)
14.3.4.1.4	Laboratory Test Results – Chemistry: Aspartate Aminotransferase (AST)
14.3.4.1.5	Laboratory Test Results – Chemistry: Bilirubin
14.3.4.1.6	Laboratory Test Results – Chemistry: Creatinine
14.3.4.1.7	Laboratory Test Results – Chemistry: Glucose
14.3.4.1.8	Laboratory Test Results – Chemistry: Hemoglobin A <sub>1c</sub>
14.3.4.1.9	Laboratory Test Results – Chemistry: Prolactin
14.3.4.1.10	Laboratory Test Results – Chemistry: Protein
14.3.4.1.11	Laboratory Test Results – Chemistry: Urea Nitrogen
14.3.4.2.1	Laboratory Test Results – Hematology: Basophils
14.3.4.2.2	Laboratory Test Results – Hematology: Basophils/Leukocytes
14.3.4.2.3	Laboratory Test Results – Hematology: Eosinophils
14.3.4.2.4	Laboratory Test Results – Hematology: Eosinophils/Leukocytes
14.3.4.2.5	Laboratory Test Results – Hematology: Hematocrit (HCT)
14.3.4.2.6	Laboratory Test Results – Hematology: Hemoglobin (HgB)
14.3.4.2.7	Laboratory Test Results – Hematology: Lymphocytes
14.3.4.2.8	Laboratory Test Results – Hematology: Lymphocytes/Leukocytes
14.3.4.2.9	Laboratory Test Results – Hematology: Monocytes
14.3.4.2.10	Laboratory Test Results – Hematology: Monocytes/Leukocytes
14.3.4.2.11	Laboratory Test Results – Hematology: Neutrophils
14.3.4.2.12	Laboratory Test Results – Hematology: Neutrophils/Leukocytes
14.3.4.2.13	Laboratory Test Results – Hematology: Platelets
14.3.4.2.14	Laboratory Test Results – Hematology: Erythrocytes
14.3.4.2.15	Laboratory Test Results – Hematology: Leukocytes
14.3.4.3.1	Laboratory Test Results – Urinalysis: Bilirubin
14.3.4.3.2	Laboratory Test Results – Urinalysis: Glucose
14.3.4.3.3	Laboratory Test Results – Urinalysis: Ketones
14.3.4.3.4	Laboratory Test Results – Urinalysis: Leukocyte Esterase
14.3.4.3.5	Laboratory Test Results – Urinalysis: Nitrite
14.3.4.3.6	Laboratory Test Results – Urinalysis: Occult Blood
14.3.4.3.7	Laboratory Test Results – Urinalysis: pH
14.3.4.3.8	Laboratory Test Results – Urinalysis: Protein
14.3.4.3.9	Laboratory Test Results – Urinalysis: Specific Gravity
14.3.4.3.10	Laboratory Test Results – Urinalysis: Urobilinogen
14.3.5.1	Vital Signs
14.3.5.2	Electrocardiogram (ECG)
14.3.5.3.1	Physical Examinations
14.3.5.3.2	Physical Examinations – Shift from Baseline
14.3.5.4	Concomitant Medications
14.3.5.5	Columbia- Suicide Severity Rating Scale (C-SSRS)

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	4.5	4.7	4.5	4.4	4.6
	SD	0.2	0.2	0.3	0.3	0.1
	Median	4.6	4.7	4.5	4.4	4.6
	Minimum	4.2	4.4	4.0	4.1	4.4
	Maximum	5	5	5	5	5
Day 0	N	6	6	6	6	6
	Mean	4.4	4.4	4.6	4.5	4.6
	SD	0.3	0.2	0.2	0.4	0.2
	Median	4.3	4.5	4.6	4.6	4.6
	Minimum	4.2	4.1	4.3	3.8	4.3
	Maximum	5	5	5	5	5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	4.6	4.6	4.5	4.6
	SD	0.2	0.3	0.2	0.4
	Median	4.7	4.6	4.5	4.6
	Minimum	4.2	4.3	4.3	4.0
	Maximum	5	5	5	5
Day 0	N	6	6	6	16
	Mean	4.5	4.4	4.4	4.4
	SD	0.3	0.3	0.1	0.3
	Median	4.5	4.4	4.4	4.5
	Minimum	4.0	4.0	4.2	3.5
	Maximum	5	5	5	5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	4.3	4.3	4.3	4.3	4.4
	SD	0.2	0.3	0.1	0.4	0.2
	Median	4.3	4.5	4.3	4.3	4.4
	Minimum	4.1	3.9	4.2	3.7	4.2
	Maximum	5	5	4	5	5
Change from Day 0	N	6	6	6	6	6
	Mean	-0.1	-0.1	-0.3	-0.2	-0.1
	SD	0.1	0.2	0.2	0.2	0.2
	Median	-0.10	-0.10	-0.30	-0.10	-0.10
	Minimum	-0.3	-0.4	-0.5	-0.5	-0.4
	Maximum	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				4.3
	SD				0.2
	Median				4.3
	Minimum				4.1
	Maximum				5
Change from Day 0	N	0	0	0	10
	Mean				-0.3
	SD				0.2
	Median				-0.25
	Minimum				-0.6
	Maximum				0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	4.5	4.2	4.5	4.4
	SD	0.3	0.3	0.3	0.3
	Median	4.5	4.1	4.5	4.6
	Minimum	4.2	3.9	4.0	4.0
	Maximum	5	5	5	5
Change from Day 0	N	6	3	5	6
	Mean	0.1	-0.1	0.1	0.2
	SD	0.4	0.2	0.4	0.3
	Median	0.05	-0.10	0.30	0.20
	Minimum	-0.4	-0.3	-0.3	-0.1
	Maximum	1	0	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	4.3	4.5	4.5	4.3	4.5
	SD	0.1	0.2	0.2	0.2	0.2
	Median	4.3	4.5	4.5	4.3	4.5
	Minimum	4.1	4.1	4.3	4.0	4.2
	Maximum	4	5	5	5	5
Change from Day 0	N	6	6	6	6	6
	Mean	-0.1	0.0	-0.1	-0.2	-0.1
	SD	0.3	0.2	0.2	0.3	0.3
	Median	-0.10	0.05	-0.05	-0.15	0.00
	Minimum	-0.7	-0.2	-0.4	-0.6	-0.5
	Maximum	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	4.7		4.2	4.6
	SD	0.2		0.4	0.3
	Median	4.6		4.2	4.7
	Minimum	4.4		3.8	4.2
	Maximum	5		5	5
Change from Day 0	N	6	0	5	14
	Mean	0.2		-0.1	0.1
	SD	0.2		0.3	0.3
	Median	0.20		-0.20	0.10
	Minimum	-0.1		-0.5	-0.2
	Maximum	1		0	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	4.5		4.2	4.4
	SD	0.2		0.2	0.5
	Median	4.5		4.2	4.6
	Minimum	4.3		3.9	3.7
	Maximum	5		4	5
Change from Day 0	N	6	0	5	4
	Mean	0.0		-0.2	0.2
	SD	0.2		0.2	0.1
	Median	0.00		-0.10	0.15
	Minimum	-0.3		-0.5	0.1
	Maximum	0		0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.1 - Laboratory Test Results - Chemistry: Albumin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		4.6	5.3	
	SD		0.2	.	
	Median		4.6	5.3	
	Minimum		4.4	5.3	
	Maximum		5	5	
Change from Day 0	N	0	3	1	0
	Mean		0.1	0.9	
	SD		0.2	.	
	Median		0.10	0.90	
	Minimum		-0.1	0.9	
	Maximum		0	1	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	70.2	57.8	68.3	77.3	67.5
	SD	10.5	11.0	8.9	23.8	15.8
	Median	67.5	57.0	70.0	83.5	64.0
	Minimum	61.0	46.0	56.0	46.0	44.0
	Maximum	88	70	79	109	86
Day 0	N	6	6	6	6	6
	Mean	66.2	57.7	67.8	73.0	68.8
	SD	10.2	11.4	12.4	17.7	17.6
	Median	66.0	58.0	63.5	79.5	67.5
	Minimum	52.0	43.0	53.0	47.0	42.0
	Maximum	81	70	83	93	93

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	79.5	60.8	75.3	65.6
	SD	19.5	15.9	22.2	18.7
	Median	80.0	59.5	77.0	64.5
	Minimum	55.0	34.0	48.0	38.0
	Maximum	108	78	101	96
Day 0	N	6	6	6	16
	Mean	77.5	59.7	73.0	62.7
	SD	17.0	14.2	21.3	15.5
	Median	78.5	58.5	73.0	61.0
	Minimum	55.0	37.0	47.0	38.0
	Maximum	103	78	97	89

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	64.2	56.0	63.2	72.0	67.8
	SD	9.5	9.9	10.1	21.2	18.3
	Median	62.5	59.0	63.0	79.5	65.5
	Minimum	52.0	44.0	48.0	43.0	39.0
	Maximum	80	68	76	97	88
Change from Day 0	N	6	6	6	6	6
	Mean	-2.0	-1.7	-4.7	-1.0	-1.0
	SD	2.2	3.8	4.9	4.3	5.2
	Median	-1.0	-1.5	-4.5	-1.0	-1.0
	Minimum	-6.0	-8.0	-12.0	-7.0	-8.0
	Maximum	0	3	3	4	5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				59.5
	SD				12.6
	Median				58.5
	Minimum				42.0
	Maximum				85
Change from Day 0	N	0	0	0	10
	Mean				-2.4
	SD				2.9
	Median				-2.5
	Minimum				-7.0
	Maximum				1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	76.7	53.0	74.2	65.0
	SD	17.9	19.7	23.4	20.5
	Median	77.0	56.0	84.0	68.0
	Minimum	52.0	32.0	43.0	37.0
	Maximum	104	71	96	93
Change from Day 0	N	6	3	5	6
	Mean	-0.8	-2.3	-2.4	1.0
	SD	6.3	2.5	1.9	3.4
	Median	-1.0	-2.0	-1.0	1.0
	Minimum	-9.0	-5.0	-5.0	-3.0
	Maximum	9	0	-1	5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	68.2	60.0	66.3	74.2	69.0
	SD	16.4	11.7	11.2	17.8	16.6
	Median	64.0	61.5	69.5	81.0	69.5
	Minimum	50.0	45.0	46.0	50.0	46.0
	Maximum	98	76	79	92	92
Change from Day 0	N	6	6	6	6	6
	Mean	2.0	2.3	-1.5	1.2	0.2
	SD	9.2	3.0	7.7	2.3	8.3
	Median	1.5	2.5	-2.0	1.5	-2.5
	Minimum	-11.0	-3.0	-12.0	-2.0	-7.0
	Maximum	17	6	7	4	15

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	77.2		70.4	67.8
	SD	17.1		21.5	16.8
	Median	79.0		69.0	64.5
	Minimum	52.0		45.0	47.0
	Maximum	102		94	101
Change from Day 0	N	6	0	5	14
	Mean	-0.3		-6.2	4.3
	SD	5.7		5.8	13.5
	Median	-1.5		-3.0	1.5
	Minimum	-7.0		-16.0	-5.0
	Maximum	10		-2	50

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	83.3		76.6	69.3
	SD	17.0		18.7	19.0
	Median	78.5		85.0	73.0
	Minimum	66.0		55.0	44.0
	Maximum	115		98	87
Change from Day 0	N	6	0	5	4
	Mean	5.8		0.0	1.8
	SD	7.0		9.0	3.6
	Median	7.5		0.0	0.5
	Minimum	-6.0		-11.0	-1.0
	Maximum	12		12	7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.2.chem.alp.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.2 - Laboratory Test Results - Chemistry: Alkaline Phosphatase (ALP)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		65.7	62.0	
	SD		12.4	.	
	Median		59.0	62.0	
	Minimum		58.0	62.0	
	Maximum		80	62	
Change from Day 0	N	0	3	1	0
	Mean		1.7	7.0	
	SD		1.5	.	
	Median		2.0	7.0	
	Minimum		0.0	7.0	
	Maximum		3	7	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.2.chem.alp.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	22.0	16.2	11.0	17.0	19.7
	SD	15.5	10.2	2.8	8.6	8.0
	Median	19.5	12.0	10.5	15.5	17.0
	Minimum	10.0	6.0	8.0	7.0	13.0
	Maximum	52	30	15	28	35
Day 0	N	6	6	6	6	6
	Mean	19.8	12.7	11.3	14.3	19.0
	SD	10.0	5.4	2.3	4.8	3.7
	Median	16.0	12.5	11.5	13.0	19.5
	Minimum	12.0	6.0	8.0	9.0	14.0
	Maximum	39	19	15	22	24

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.3.chem.alt.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	20.5	19.5	14.8	22.7
	SD	4.7	9.0	3.4	9.0
	Median	20.0	17.5	14.5	21.5
	Minimum	15.0	10.0	11.0	9.0
	Maximum	29	34	21	39
Day 0	N	6	6	6	16
	Mean	20.0	17.2	13.5	18.4
	SD	8.1	11.9	4.8	8.2
	Median	17.0	12.5	14.0	17.0
	Minimum	13.0	10.0	7.0	7.0
	Maximum	32	41	20	38

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	21.5	11.7	11.3	12.2	18.3
	SD	12.8	4.2	2.9	4.5	4.6
	Median	16.5	12.5	12.0	11.0	18.0
	Minimum	9.0	6.0	7.0	6.0	12.0
	Maximum	41	16	15	18	24
Change from Day 0	N	6	6	6	6	6
	Mean	1.7	-1.0	0.0	-2.2	-0.7
	SD	5.0	1.7	2.4	1.5	2.0
	Median	0.5	0.0	0.0	-2.5	-1.0
	Minimum	-3.0	-4.0	-3.0	-4.0	-3.0
	Maximum	11	0	3	0	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.3.chem.alt.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				19.1
	SD				6.6
	Median				16.5
	Minimum				12.0
	Maximum				31
Change from Day 0	N	0	0	0	10
	Mean				-1.5
	SD				3.2
	Median				-1.5
	Minimum				-7.0
	Maximum				3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	24.7	21.0	15.8	19.7
	SD	16.1	12.3	5.0	7.2
	Median	20.5	16.0	18.0	22.0
	Minimum	13.0	12.0	7.0	9.0
	Maximum	56	35	19	28
Change from Day 0	N	6	3	5	6
	Mean	4.7	-1.0	1.0	4.8
	SD	10.0	4.6	3.3	5.2
	Median	1.0	0.0	0.0	4.0
	Minimum	-4.0	-6.0	-2.0	-2.0
	Maximum	24	3	5	13

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	20.3	15.2	11.0	14.0	19.3
	SD	8.5	7.1	2.5	5.5	6.1
	Median	19.0	14.5	10.0	13.5	18.5
	Minimum	12.0	8.0	9.0	7.0	12.0
	Maximum	36	26	16	21	30
Change from Day 0	N	6	6	6	6	6
	Mean	0.5	2.5	-0.3	-0.3	0.3
	SD	3.9	2.4	1.2	5.5	4.4
	Median	0.0	2.0	-0.5	-2.0	-1.0
	Minimum	-3.0	0.0	-2.0	-6.0	-3.0
	Maximum	8	7	1	10	9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	21.5		12.2	22.6
	SD	12.9		3.6	7.2
	Median	17.5		14.0	20.5
	Minimum	12.0		6.0	11.0
	Maximum	47		15	37
Change from Day 0	N	6	0	5	14
	Mean	1.5		-2.6	2.9
	SD	8.5		2.2	5.9
	Median	0.5		-2.0	3.0
	Minimum	-11.0		-6.0	-6.0
	Maximum	15		0	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.3.chem.alt.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	21.2		16.6	21.8
	SD	7.5		4.4	9.8
	Median	18.0		18.0	18.5
	Minimum	15.0		9.0	14.0
	Maximum	32		20	36
Change from Day 0	N	6	0	5	4
	Mean	1.2		1.8	4.5
	SD	7.9		3.0	9.2
	Median	2.5		0.0	3.0
	Minimum	-13.0		-1.0	-5.0
	Maximum	11		6	17

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.3.chem.alt.sas



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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.3 - Laboratory Test Results - Chemistry: Alanine Aminotransferase (ALT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		13.7	11.0	
	SD		7.2	.	
	Median		10.0	11.0	
	Minimum		9.0	11.0	
	Maximum		22	11	
Change from Day 0	N	0	3	1	0
	Mean		1.3	4.0	
	SD		4.0	.	
	Median		-1.0	4.0	
	Minimum		-1.0	4.0	
	Maximum		6	4	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.3.chem.alt.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	21.8	21.5	18.0	19.2	23.8
	SD	7.5	6.0	3.6	8.8	6.4
	Median	19.5	21.5	17.5	18.5	24.5
	Minimum	14.0	14.0	14.0	10.0	15.0
	Maximum	36	30	23	34	31
Day 0	N	6	6	6	6	6
	Mean	20.2	16.5	18.0	16.8	21.5
	SD	6.2	4.3	3.6	5.7	5.9
	Median	17.5	16.0	16.5	15.5	21.5
	Minimum	15.0	11.0	14.0	11.0	14.0
	Maximum	31	23	23	26	28

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.4.chem.ast.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	21.8	23.5	19.7	20.4
	SD	1.6	6.5	3.1	3.9
	Median	22.0	23.0	19.0	21.0
	Minimum	20.0	16.0	17.0	11.0
	Maximum	24	35	25	24
Day 0	N	6	6	6	16
	Mean	20.2	23.7	17.0	19.7
	SD	3.7	5.5	2.6	5.4
	Median	19.0	24.5	17.5	19.0
	Minimum	16.0	17.0	12.0	11.0
	Maximum	26	32	19	31

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	21.2	15.7	14.7	13.8	20.8
	SD	6.6	3.5	2.6	4.3	6.0
	Median	19.5	17.0	14.5	12.5	20.0
	Minimum	15.0	10.0	11.0	9.0	13.0
	Maximum	33	19	19	20	31
Change from Day 0	N	6	6	6	6	6
	Mean	1.0	-0.8	-3.3	-3.0	-0.7
	SD	5.1	2.4	2.0	2.4	2.9
	Median	1.0	-1.0	-2.5	-3.5	0.0
	Minimum	-7.0	-5.0	-7.0	-6.0	-4.0
	Maximum	9	2	-2	1	3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				18.0
	SD				3.6
	Median				18.0
	Minimum				13.0
	Maximum				25
Change from Day 0	N	0	0	0	10
	Mean				-3.3
	SD				3.8
	Median				-2.0
	Minimum				-11.0
	Maximum				1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	20.7	16.3	16.0	18.5
	SD	6.5	4.0	3.2	9.1
	Median	18.5	17.0	16.0	15.5
	Minimum	15.0	12.0	11.0	13.0
	Maximum	33	20	20	37
Change from Day 0	N	6	3	5	6
	Mean	0.5	-9.0	-1.0	1.5
	SD	4.8	7.0	1.4	6.9
	Median	-1.0	-12.0	-1.0	-0.5
	Minimum	-4.0	-14.0	-3.0	-4.0
	Maximum	10	-1	1	15

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	23.5	19.0	16.2	15.5	21.7
	SD	6.3	5.1	3.3	4.5	6.5
	Median	22.0	18.5	15.0	14.5	22.0
	Minimum	17.0	12.0	13.0	11.0	13.0
	Maximum	35	26	22	23	28
Change from Day 0	N	6	6	6	6	6
	Mean	3.3	2.5	-1.8	-1.3	0.2
	SD	8.7	1.5	3.7	2.9	1.7
	Median	2.0	2.5	-1.0	-3.0	0.0
	Minimum	-7.0	1.0	-9.0	-3.0	-2.0
	Maximum	19	5	1	4	3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	20.8		15.2	20.7
	SD	2.8		3.1	4.9
	Median	20.5		16.0	21.0
	Minimum	18.0		10.0	13.0
	Maximum	26		18	33
Change from Day 0	N	6	0	5	14
	Mean	0.7		-1.8	0.2
	SD	3.4		1.1	3.7
	Median	2.5		-2.0	0.0
	Minimum	-5.0		-3.0	-6.0
	Maximum	3		0	7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	22.8		19.2	20.0
	SD	3.3		3.6	2.6
	Median	22.5		20.0	20.0
	Minimum	19.0		13.0	17.0
	Maximum	27		22	23
Change from Day 0	N	6	0	5	4
	Mean	2.7		2.2	1.5
	SD	4.8		1.8	2.9
	Median	3.0		1.0	1.5
	Minimum	-6.0		1.0	-2.0
	Maximum	9		5	5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.4 - Laboratory Test Results - Chemistry: Aspartate Aminotransferase (AST)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		22.0	22.0	
	SD		6.9	.	
	Median		18.0	22.0	
	Minimum		18.0	22.0	
	Maximum		30	22	
Change from Day 0	N	0	3	1	0
	Mean		0.0	5.0	
	SD		5.6	.	
	Median		1.0	5.0	
	Minimum		-6.0	5.0	
	Maximum		5	5	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	5	6	5	6
	Mean	0.4	0.6	0.5	0.6	0.5
	SD	0.1	0.3	0.3	0.3	0.2
	Median	0.5	0.4	0.5	0.7	0.5
	Minimum	0.3	0.3	0.2	0.3	0.2
	Maximum	1	1	1	1	1
Day 0	N	5	4	5	6	6
	Mean	0.4	0.4	0.8	0.5	0.6
	SD	0.1	0.1	0.5	0.3	0.2
	Median	0.4	0.4	0.6	0.6	0.6
	Minimum	0.2	0.3	0.4	0.2	0.3
	Maximum	1	1	2	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	5	16
	Mean	0.5	0.6	0.6	0.5
	SD	0.2	0.3	0.3	0.3
	Median	0.5	0.6	0.5	0.4
	Minimum	0.3	0.2	0.3	0.2
	Maximum	1	1	1	1
Day 0	N	6	5	6	15
	Mean	0.3	0.5	0.4	0.5
	SD	0.1	0.3	0.2	0.3
	Median	0.3	0.5	0.4	0.5
	Minimum	0.2	0.3	0.2	0.2
	Maximum	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	5	4	6	6	5
	Mean	0.4	0.6	0.5	0.5	0.5
	SD	0.2	0.2	0.2	0.2	0.3
	Median	0.4	0.5	0.4	0.4	0.4
	Minimum	0.2	0.5	0.2	0.2	0.2
	Maximum	1	1	1	1	1
Change from Day 0	N	4	4	5	6	5
	Mean	0.1	0.2	-0.3	-0.1	-0.1
	SD	0.2	0.1	0.3	0.2	0.1
	Median	0.1	0.2	-0.2	0.0	0.0
	Minimum	-0.1	0.1	-0.7	-0.4	-0.3
	Maximum	0.2	0.3	0.0	0.1	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	8
	Mean				0.4
	SD				0.2
	Median				0.3
	Minimum				0.2
	Maximum				1
Change from Day 0	N	0	0	0	8
	Mean				-0.2
	SD				0.2
	Median				-0.1
	Minimum				-0.7
	Maximum				0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	4	6
	Mean	0.5	0.4	0.4	0.6
	SD	0.2	0.2	0.2	0.2
	Median	0.6	0.5	0.4	0.6
	Minimum	0.3	0.2	0.2	0.3
	Maximum	1	1	1	1
Change from Day 0	N	6	2	4	5
	Mean	0.2	0.0	0.1	-0.0
	SD	0.1	0.0	0.1	0.2
	Median	0.1	0.0	0.1	0.0
	Minimum	0.1	0.0	0.0	-0.4
	Maximum	0.4	0.0	0.2	0.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	4	5	3	5	6
	Mean	0.4	0.3	0.6	0.6	0.4
	SD	0.1	0.0	0.3	0.3	0.2
	Median	0.4	0.3	0.5	0.4	0.4
	Minimum	0.3	0.3	0.3	0.3	0.2
	Maximum	1	0	1	1	1
Change from Day 0	N	4	4	3	5	6
	Mean	0.0	-0.1	-0.4	-0.0	-0.2
	SD	0.1	0.2	0.3	0.3	0.2
	Median	0.1	-0.1	-0.3	0.0	-0.1
	Minimum	-0.2	-0.3	-0.7	-0.4	-0.4
	Maximum	0.1	0.1	-0.2	0.3	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	4	13
	Mean	0.6		0.4	0.4
	SD	0.2		0.2	0.1
	Median	0.6		0.4	0.4
	Minimum	0.3		0.3	0.2
	Maximum	1		1	1
Change from Day 0	N	6	0	4	12
	Mean	0.2		0.1	-0.1
	SD	0.1		0.2	0.2
	Median	0.2		0.1	-0.1
	Minimum	0.1		-0.2	-0.5
	Maximum	0.4		0.2	0.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	5	0	3	3
	Mean	0.4		0.3	0.4
	SD	0.1		0.1	0.1
	Median	0.4		0.3	0.4
	Minimum	0.3		0.3	0.3
	Maximum	1		0	0
Change from Day 0	N	5	0	3	3
	Mean	0.0		-0.1	-0.0
	SD	0.1		0.2	0.1
	Median	0.1		-0.2	0.0
	Minimum	-0.1		-0.2	-0.1
	Maximum	0.1		0.1	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.5 - Laboratory Test Results - Chemistry: Bilirubin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		0.4	0.5	
	SD		0.1	.	
	Median		0.4	0.5	
	Minimum		0.4	0.5	
	Maximum		1	1	
Change from Day 0	N	0	3	1	0
	Mean		-0.1	-0.1	
	SD		0.3	.	
	Median		0.1	-0.1	
	Minimum		-0.5	-0.1	
	Maximum		0.1	-0.1	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	0.9	0.9	1.0	1.0	1.1
	SD	0.1	0.2	0.2	0.2	0.2
	Median	0.9	1.0	1.1	0.9	1.1
	Minimum	0.8	0.7	0.7	0.8	0.8
	Maximum	1	1	1	1	1
Day 0	N	6	6	6	6	6
	Mean	0.8	0.9	1.0	1.0	1.1
	SD	0.2	0.2	0.3	0.1	0.2
	Median	0.8	1.0	1.1	0.9	1.0
	Minimum	0.7	0.7	0.7	0.8	0.8
	Maximum	1	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	1.0	0.9	0.8	1.0
	SD	0.2	0.2	0.2	0.2
	Median	1.0	1.0	0.9	1.0
	Minimum	0.9	0.7	0.6	0.7
	Maximum	1	1	1	1
Day 0	N	6	6	6	16
	Mean	1.0	0.9	0.8	1.0
	SD	0.2	0.1	0.1	0.2
	Median	1.0	1.0	0.8	1.1
	Minimum	0.9	0.7	0.7	0.5
	Maximum	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	0.9	0.9	1.0	1.0	1.1
	SD	0.1	0.2	0.3	0.2	0.2
	Median	0.9	0.9	1.1	1.0	1.1
	Minimum	0.7	0.6	0.7	0.8	0.9
	Maximum	1	1	1	1	2
Change from Day 0	N	6	6	6	6	6
	Mean	0.05	-0.05	0.03	0.06	0.09
	SD	0.0	0.1	0.0	0.1	0.0
	Median	0.06	-0.06	0.03	0.06	0.08
	Minimum	-0.02	-0.15	0.00	-0.05	0.03
	Maximum	0.1	0.1	0.1	0.2	0.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				1.0
	SD				0.3
	Median				1.1
	Minimum				0.6
	Maximum				1
Change from Day 0	N	0	0	0	10
	Mean				0.03
	SD				0.1
	Median				0.02
	Minimum				-0.08
	Maximum				0.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	1.1	1.0	0.9	1.1
	SD	0.2	0.2	0.1	0.2
	Median	1.0	1.1	0.8	1.1
	Minimum	1.0	0.9	0.7	0.8
	Maximum	1	1	1	1
Change from Day 0	N	6	3	5	6
	Mean	0.07	0.04	0.06	0.02
	SD	0.1	0.1	0.1	0.1
	Median	0.07	0.00	0.04	0.01
	Minimum	0.00	-0.01	0.00	-0.05
	Maximum	0.2	0.1	0.2	0.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	0.8	0.9	1.0	1.0	1.1
	SD	0.1	0.2	0.3	0.1	0.2
	Median	0.8	1.0	1.0	0.9	1.1
	Minimum	0.7	0.7	0.7	0.8	0.7
	Maximum	1	1	1	1	1
Change from Day 0	N	6	6	6	6	6
	Mean	-0.04	-0.01	-0.03	0.03	0.00
	SD	0.1	0.0	0.0	0.1	0.1
	Median	-0.03	-0.01	-0.02	0.02	0.00
	Minimum	-0.17	-0.07	-0.12	-0.03	-0.09
	Maximum	0.1	0.0	0.0	0.1	0.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	1.1		0.9	1.0
	SD	0.2		0.1	0.2
	Median	1.0		0.9	1.1
	Minimum	0.9		0.8	0.6
	Maximum	1		1	1
Change from Day 0	N	6	0	5	14
	Mean	0.03		0.09	0.02
	SD	0.1		0.1	0.1
	Median	0.06		0.08	0.02
	Minimum	-0.10		0.03	-0.11
	Maximum	0.1		0.2	0.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.6.chem.crt.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	1.1		0.9	1.2
	SD	0.2		0.2	0.2
	Median	1.0		0.9	1.2
	Minimum	1.0		0.8	1.0
	Maximum	1		1	1
Change from Day 0	N	6	0	5	4
	Mean	0.04		0.12	0.06
	SD	0.0		0.0	0.1
	Median	0.03		0.11	0.06
	Minimum	-0.01		0.07	0.00
	Maximum	0.1		0.2	0.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.6 - Laboratory Test Results - Chemistry: Creatinine

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		1.0	1.2	
	SD		0.2	.	
	Median		1.1	1.2	
	Minimum		0.8	1.2	
	Maximum		1	1	
Change from Day 0	N	0	3	1	0
	Mean		0.10	0.14	
	SD		0.1	.	
	Median		0.06	0.14	
	Minimum		0.06	0.14	
	Maximum		0.2	0.1	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	87.5	88.0	85.8	82.7	89.8
	SD	7.3	7.6	7.7	3.1	6.7
	Median	86.5	88.0	85.0	82.5	89.0
	Minimum	78.0	77.0	74.0	79.0	81.0
	Maximum	97	99	96	86	99
Day 0	N	6	6	6	6	6
	Mean	86.5	92.2	83.3	85.0	90.5
	SD	2.7	13.3	6.1	9.4	6.6
	Median	86.5	90.0	84.0	82.0	89.5
	Minimum	83.0	72.0	73.0	77.0	82.0
	Maximum	90	107	90	102	100

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.7.chem.gluc.sas

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	87.2	88.2	83.5	91.6
	SD	6.9	7.7	3.7	5.0
	Median	86.5	91.0	84.0	91.5
	Minimum	78.0	76.0	77.0	81.0
	Maximum	99	96	88	99
Day 0	N	6	6	6	16
	Mean	92.7	87.5	85.8	90.0
	SD	13.4	5.0	5.5	6.8
	Median	96.5	86.0	87.0	92.0
	Minimum	68.0	83.0	78.0	80.0
	Maximum	103	95	91	102

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	91.8	88.3	84.3	87.8	87.0
	SD	6.3	9.4	4.2	2.6	4.3
	Median	92.5	86.5	83.5	88.5	86.5
	Minimum	83.0	78.0	79.0	84.0	82.0
	Maximum	102	106	91	90	93
Change from Day 0	N	6	6	6	6	6
	Mean	5.3	-3.8	1.0	2.8	-3.5
	SD	5.1	9.5	5.5	7.8	6.0
	Median	4.0	-1.5	-0.5	6.0	-1.5
	Minimum	0.0	-22.0	-5.0	-12.0	-14.0
	Maximum	15	6	9	9	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				90.4
	SD				5.4
	Median				90.0
	Minimum				83.0
	Maximum				100
Change from Day 0	N	0	0	0	10
	Mean				1.8
	SD				5.6
	Median				1.0
	Minimum				-7.0
	Maximum				10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	86.7	90.3	87.2	88.7
	SD	4.7	5.9	4.8	6.0
	Median	87.5	88.0	87.0	87.0
	Minimum	80.0	86.0	82.0	83.0
	Maximum	91	97	95	99
Change from Day 0	N	6	3	5	6
	Mean	-6.0	2.0	-0.2	-3.7
	SD	11.4	11.5	4.8	6.0
	Median	-11.0	1.0	-3.0	-4.0
	Minimum	-12.0	-9.0	-4.0	-10.0
	Maximum	17	14	6	3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	85.5	87.8	86.5	90.5	91.0
	SD	8.3	9.6	8.9	6.3	6.5
	Median	82.0	91.0	84.0	90.5	90.0
	Minimum	78.0	76.0	75.0	82.0	83.0
	Maximum	97	98	101	101	102
Change from Day 0	N	6	6	6	6	6
	Mean	-1.0	-4.3	3.2	5.5	0.5
	SD	7.1	8.2	5.3	4.0	7.6
	Median	-4.5	-3.5	2.0	6.5	-1.0
	Minimum	-8.0	-14.0	-3.0	-1.0	-10.0
	Maximum	8	4	13	9	12

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	88.2		84.4	89.6
	SD	3.8		2.6	8.3
	Median	88.5		83.0	86.0
	Minimum	84.0		83.0	80.0
	Maximum	93		89	108
Change from Day 0	N	6	0	5	14
	Mean	-4.5		-3.0	0.1
	SD	11.7		3.6	9.1
	Median	-8.5		-2.0	1.5
	Minimum	-12.0		-7.0	-18.0
	Maximum	19		2	13

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	92.2		88.0	98.0
	SD	14.5		9.3	9.6
	Median	94.5		86.0	96.0
	Minimum	69.0		77.0	89.0
	Maximum	108		101	111
Change from Day 0	N	6	0	5	4
	Mean	-0.5		0.6	6.3
	SD	7.1		10.4	9.6
	Median	1.0		2.0	6.5
	Minimum	-11.0		-14.0	-3.0
	Maximum	7		12	15

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.7 - Laboratory Test Results - Chemistry: Glucose

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		110.3	89.0	
	SD		24.2	.	
	Median		119.0	89.0	
	Minimum		83.0	89.0	
	Maximum		129	89	
Change from Day 0	N	0	3	1	0
	Mean		23.7	11.0	
	SD		22.2	.	
	Median		36.0	11.0	
	Minimum		-2.0	11.0	
	Maximum		37	11	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.8 - Laboratory Test Results - Chemistry: Hemoglobin A1C/Hemoglobin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	5.2	5.1	5.1	5.4	5.4
	SD	0.3	0.5	0.3	0.1	0.2
	Median	5.2	5.1	5.1	5.4	5.4
	Minimum	4.7	4.6	4.7	5.3	5.1
	Maximum	6	6	6	5	6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.8.chem.ha1c.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.4.1.8 - Laboratory Test Results - Chemistry: Hemoglobin A1C/Hemoglobin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	5.3	5.1	5.3	5.3
	SD	0.4	0.3	0.2	0.3
	Median	5.4	5.2	5.2	5.4
	Minimum	4.7	4.6	5.1	4.7
	Maximum	6	6	6	6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.8.chem.ha1c.sas

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	11.2	10.2	7.6	11.7	8.9
	SD	4.6	9.0	1.2	2.7	3.2
	Median	10.0	7.0	7.8	11.8	8.2
	Minimum	7.2	5.3	5.5	8.8	5.7
	Maximum	20	29	9	15	13
Day 3	N	6	6	6	6	6
	Mean	95.3	52.9	56.3	56.8	56.9
	SD	52.2	29.8	42.9	31.3	33.1
	Median	90.5	37.0	34.2	46.1	51.2
	Minimum	38.3	31.7	23.0	23.5	20.8
	Maximum	160	105	130	96	118

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.9.chem.prol.sas

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	10.2	11.3	10.3	9.8
	SD	2.1	6.1	5.6	4.1
	Median	10.0	8.9	7.7	9.2
	Minimum	7.4	7.2	6.4	4.1
	Maximum	14	23	21	20
Day 3	N	0	0	0	10
	Mean				19.3
	SD				12.6
	Median				13.1
	Minimum				7.9
	Maximum				43

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 8	N	0	6	6	6	6
	Mean		12.9	17.5	49.7	75.7
	SD		3.7	5.6	26.8	74.6
	Median		12.6	15.4	46.8	45.7
	Minimum		9.3	12.0	18.4	25.6
	Maximum		18	27	81	223

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	59.9	46.8	76.9	17.3
	SD	17.0	12.0	48.1	5.5
	Median	64.6	42.6	55.7	17.2
	Minimum	35.4	37.5	32.4	11.3
	Maximum	83	60	146	26
Day 8	N	0	0	0	8
	Mean				15.9
	SD				8.6
	Median				13.9
	Minimum				7.8
	Maximum				32

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 9	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 15	N	0	0	0	0	6
	Mean					34.4
	SD					20.2
	Median					27.0
	Minimum					18.8
	Maximum					72

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 9	N	6	0	5	4
	Mean	86.8		122.8	24.4
	SD	37.0		79.9	12.9
	Median	87.6		90.6	23.0
	Minimum	43.5		45.1	11.3
	Maximum	148		209	40
Day 15	N	6	0	5	6
	Mean	42.9		49.3	11.7
	SD	20.9		28.0	3.3
	Median	41.9		45.0	11.7
	Minimum	18.4		24.4	6.4
	Maximum	68		94	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.9 - Laboratory Test Results - Chemistry: Prolactin

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	0	1	0
	Mean			31.5	
	SD			.	
	Median			31.5	
	Minimum			31.5	
	Maximum			32	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	7.0	7.0	7.0	7.0	7.2
	SD	0.2	0.2	0.6	0.3	0.5
	Median	7.0	7.0	7.0	7.1	7.4
	Minimum	6.6	6.8	6.3	6.5	6.3
	Maximum	7	7	8	7	8
Day 0	N	6	6	6	6	6
	Mean	6.9	6.6	6.9	7.3	7.0
	SD	0.5	0.2	0.5	0.4	0.3
	Median	6.9	6.6	6.8	7.2	6.9
	Minimum	6.2	6.2	6.3	6.8	6.7
	Maximum	8	7	8	8	8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.10.chem.prot.sas

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	7.3	7.4	7.1	6.9
	SD	0.7	0.5	0.3	0.7
	Median	7.5	7.3	7.2	7.1
	Minimum	6.0	7.0	6.6	5.4
	Maximum	8	8	7	8
Day 0	N	6	6	6	16
	Mean	7.0	7.0	6.8	6.8
	SD	0.6	0.7	0.3	0.7
	Median	7.1	6.8	6.8	6.9
	Minimum	5.9	6.3	6.4	5.3
	Maximum	8	8	7	8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.10.chem.prot.sas

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	7.0	6.8	6.5	6.9	7.1
	SD	0.4	0.3	0.2	0.4	0.4
	Median	6.9	6.8	6.5	7.0	7.1
	Minimum	6.6	6.4	6.3	6.3	6.5
	Maximum	8	7	7	7	8
Change from Day 0	N	6	6	6	6	6
	Mean	0.1	0.2	-0.4	-0.4	0.0
	SD	0.2	0.3	0.4	0.3	0.3
	Median	0.10	0.20	-0.35	-0.30	0.15
	Minimum	-0.2	-0.2	-1.1	-0.8	-0.4
	Maximum	0	1	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.10.chem.prot.sas

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				6.8
	SD				0.5
	Median				6.8
	Minimum				5.9
	Maximum				8
Change from Day 0	N	0	0	0	10
	Mean				-0.3
	SD				0.4
	Median				-0.35
	Minimum				-0.9
	Maximum				0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.10.chem.prot.sas



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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	7.3	6.4	7.1	6.8
	SD	0.4	0.5	0.8	0.6
	Median	7.3	6.3	7.1	6.9
	Minimum	6.9	6.0	6.0	6.1
	Maximum	8	7	8	8
Change from Day 0	N	6	3	5	6
	Mean	0.3	-0.2	0.2	0.4
	SD	0.6	0.3	0.6	0.4
	Median	0.25	0.00	0.40	0.50
	Minimum	-0.4	-0.5	-0.4	-0.1
	Maximum	1	0	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	6.9	6.8	6.7	6.9	6.9
	SD	0.4	0.3	0.2	0.3	0.4
	Median	6.9	6.8	6.7	6.9	7.0
	Minimum	6.2	6.5	6.5	6.6	6.3
	Maximum	7	7	7	7	7
Change from Day 0	N	6	6	6	6	6
	Mean	-0.1	0.2	-0.2	-0.4	-0.1
	SD	0.5	0.3	0.4	0.4	0.5
	Median	0.00	0.30	-0.05	-0.30	-0.05
	Minimum	-1.1	-0.3	-0.7	-1.1	-0.9
	Maximum	0	0	0	0	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.1.10.chem.prot.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	7.5		6.7	7.0
	SD	0.4		0.6	0.4
	Median	7.6		6.7	7.0
	Minimum	6.8		5.9	6.3
	Maximum	8		8	8
Change from Day 0	N	6	0	5	14
	Mean	0.5		-0.1	0.1
	SD	0.4		0.3	0.4
	Median	0.50		-0.10	0.05
	Minimum	0.0		-0.5	-0.5
	Maximum	1		0	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	7.1		6.8	6.8
	SD	0.3		0.3	0.9
	Median	7.1		6.8	7.0
	Minimum	6.6		6.4	5.5
	Maximum	7		7	8
Change from Day 0	N	6	0	5	4
	Mean	0.1		-0.1	0.2
	SD	0.4		0.4	0.1
	Median	0.10		0.10	0.20
	Minimum	-0.4		-0.6	0.2
	Maximum	1		0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.10 - Laboratory Test Results - Chemistry: Protein

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		7.5	7.8	
	SD		0.6	.	
	Median		7.5	7.8	
	Minimum		7.0	7.8	
	Maximum		8	8	
Change from Day 0	N	0	3	1	0
	Mean		0.1	1.3	
	SD		0.3	.	
	Median		0.20	1.30	
	Minimum		-0.2	1.3	
	Maximum		0	1	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	12.0	12.7	11.2	11.7	10.2
	SD	3.4	3.2	3.5	2.1	3.6
	Median	12.5	11.5	10.5	11.0	9.5
	Minimum	6.0	10.0	7.0	9.0	6.0
	Maximum	16	18	17	15	16
Day 0	N	6	6	6	6	6
	Mean	13.3	12.7	11.0	11.0	10.3
	SD	3.9	4.2	2.4	1.3	2.3
	Median	12.5	11.5	11.0	11.5	11.5
	Minimum	9.0	10.0	8.0	9.0	7.0
	Maximum	19	21	15	12	12

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	13.3	11.3	11.2	12.4
	SD	2.2	1.9	3.9	3.2
	Median	13.5	12.0	12.5	13.0
	Minimum	10.0	9.0	6.0	7.0
	Maximum	16	13	15	20
Day 0	N	6	6	6	16
	Mean	14.2	13.0	12.8	13.7
	SD	1.6	3.1	4.2	3.1
	Median	14.0	12.0	12.5	14.0
	Minimum	12.0	10.0	8.0	10.0
	Maximum	16	19	18	21

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	15.7	15.2	14.0	11.0	13.7
	SD	4.3	1.8	2.8	2.0	1.0
	Median	16.5	15.5	14.5	11.0	14.0
	Minimum	8.0	13.0	10.0	9.0	12.0
	Maximum	20	17	17	14	15
Change from Day 0	N	6	6	6	6	6
	Mean	2.3	2.5	3.0	0.0	3.3
	SD	5.5	3.6	1.3	2.5	3.0
	Median	1.5	3.5	2.5	0.5	2.5
	Minimum	-3.0	-4.0	2.0	-3.0	0.0
	Maximum	10	6	5	3	7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				15.2
	SD				2.6
	Median				15.0
	Minimum				11.0
	Maximum				19
Change from Day 0	N	0	0	0	10
	Mean				1.7
	SD				2.5
	Median				1.5
	Minimum				-2.0
	Maximum				7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	15.7	13.7	13.4	14.0
	SD	1.4	0.6	3.0	2.2
	Median	16.0	14.0	13.0	13.5
	Minimum	14.0	13.0	10.0	11.0
	Maximum	17	14	18	17
Change from Day 0	N	6	3	5	6
	Mean	1.5	-1.0	0.8	0.0
	SD	1.4	4.4	3.1	4.6
	Median	1.5	1.0	0.0	1.5
	Minimum	0.0	-6.0	-3.0	-7.0
	Maximum	3	2	4	5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	11.3	13.2	12.0	11.8	11.0
	SD	2.3	3.2	2.6	2.5	1.9
	Median	11.5	12.5	12.5	11.5	11.0
	Minimum	8.0	10.0	8.0	9.0	9.0
	Maximum	15	19	15	16	13
Change from Day 0	N	6	6	6	6	6
	Mean	-2.0	0.5	1.0	0.8	0.7
	SD	2.5	1.4	1.8	2.2	1.5
	Median	-1.0	1.0	0.5	0.0	1.0
	Minimum	-7.0	-2.0	-1.0	-2.0	-2.0
	Maximum	0	2	4	4	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	18.0		15.0	14.0
	SD	0.6		3.1	4.4
	Median	18.0		15.0	12.5
	Minimum	17.0		12.0	8.0
	Maximum	19		20	21
Change from Day 0	N	6	0	5	14
	Mean	3.8		2.4	0.6
	SD	1.8		3.2	5.0
	Median	3.5		2.0	-0.5
	Minimum	2.0		-2.0	-5.0
	Maximum	6		6	9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	15.8		11.2	12.5
	SD	2.6		3.6	2.4
	Median	14.5		10.0	12.5
	Minimum	14.0		7.0	10.0
	Maximum	20		15	15
Change from Day 0	N	6	0	5	4
	Mean	1.7		-1.4	-0.8
	SD	2.6		5.3	3.4
	Median	1.5		-2.0	-1.5
	Minimum	-2.0		-8.0	-4.0
	Maximum	5		6	4

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Protocol: LB-102-001

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.1.11 - Laboratory Test Results - Chemistry: Urea Nitrogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		13.0	16.0	
	SD		2.0	.	
	Median		13.0	16.0	
	Minimum		11.0	16.0	
	Maximum		15	16	
Change from Day 0	N	0	3	1	0
	Mean		1.7	2.0	
	SD		1.2	.	
	Median		1.0	2.0	
	Minimum		1.0	2.0	
	Maximum		3	2	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	0.00	0.02	0.00	0.00	0.02
	SD	0.00	0.04	0.00	0.00	0.04
	Median	0.00	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	0.00	0.10	0.00	0.00	0.10
Day 0	N	6	6	6	6	6
	Mean	0.00	0.02	0.00	0.00	0.03
	SD	0.00	0.04	0.00	0.00	0.05
	Median	0.00	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	0.00	0.10	0.00	0.00	0.10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	0.02	0.00	0.02	0.02
	SD	0.04	0.00	0.04	0.04
	Median	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00
	Maximum	0.10	0.00	0.10	0.10
Day 0	N	6	6	6	16
	Mean	0.00	0.00	0.02	0.01
	SD	0.00	0.00	0.04	0.03
	Median	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00
	Maximum	0.00	0.00	0.10	0.10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	0.03	0.02	0.00	0.00	0.00
	SD	0.05	0.04	0.00	0.00	0.00
	Median	0.00	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	0.10	0.10	0.00	0.00	0.00
Change from Day 0	N	6	6	6	6	6
	Mean	0.03	0.00	0.00	0.00	-0.03
	SD	0.05	0.00	0.00	0.00	0.05
	Median	0.00	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00	-0.10
	Maximum	0.10	0.00	0.00	0.00	0.00

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				0.00
	SD				0.00
	Median				0.00
	Minimum				0.00
	Maximum				0.00
Change from Day 0	N	0	0	0	10
	Mean				0.00
	SD				0.00
	Median				0.00
	Minimum				0.00
	Maximum				0.00

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	0.00	0.00	0.04	0.02
	SD	0.00	0.00	0.05	0.04
	Median	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00
	Maximum	0.00	0.00	0.10	0.10
Change from Day 0	N	6	3	5	6
	Mean	0.00	0.00	0.02	0.00
	SD	0.00	0.00	0.04	0.00
	Median	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00
	Maximum	0.00	0.00	0.10	0.00

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	0.02	0.02	0.00	0.00	0.03
	SD	0.04	0.04	0.00	0.00	0.05
	Median	0.00	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	0.10	0.10	0.00	0.00	0.10
Change from Day 0	N	6	6	6	6	6
	Mean	0.02	0.00	0.00	0.00	0.00
	SD	0.04	0.00	0.00	0.00	0.06
	Median	0.00	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	0.00	0.00	-0.10
	Maximum	0.10	0.00	0.00	0.00	0.10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	0.00		0.00	0.01
	SD	0.00		0.00	0.03
	Median	0.00		0.00	0.00
	Minimum	0.00		0.00	0.00
	Maximum	0.00		0.00	0.10
Change from Day 0	N	6	0	5	14
	Mean	0.00		-0.02	0.01
	SD	0.00		0.04	0.03
	Median	0.00		0.00	0.00
	Minimum	0.00		-0.10	0.00
	Maximum	0.00		0.00	0.10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	0.00		0.02	0.03
	SD	0.00		0.04	0.05
	Median	0.00		0.00	0.00
	Minimum	0.00		0.00	0.00
	Maximum	0.00		0.10	0.10
Change from Day 0	N	6	0	5	4
	Mean	0.00		0.00	0.03
	SD	0.00		0.00	0.05
	Median	0.00		0.00	0.00
	Minimum	0.00		0.00	0.00
	Maximum	0.00		0.00	0.10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.1 - Laboratory Test Results - Hematology: Basophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		0.00	0.00	
	SD		0.00	.	
	Median		0.00	0.00	
	Minimum		0.00	0.00	
	Maximum		0.00	0.00	
Change from Day 0	N	0	3	1	0
	Mean		0.00	0.00	
	SD		0.00	.	
	Median		0.00	0.00	
	Minimum		0.00	0.00	
	Maximum		0.00	0.00	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	0.67	0.17	0.17	0.33	0.67
	SD	0.52	0.41	0.41	0.52	0.52
	Median	1.00	0.00	0.00	0.00	1.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	1	1	1	1	1
Day 0	N	6	6	6	6	6
	Mean	0.17	0.33	0.17	0.50	0.67
	SD	0.41	0.52	0.41	0.55	0.52
	Median	0.00	0.00	0.00	0.50	1.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	1	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	0.33	0.17	0.83	0.44
	SD	0.52	0.41	0.41	0.51
	Median	0.00	0.00	1.00	0.00
	Minimum	0.00	0.00	0.00	0.00
	Maximum	1	1	1	1
Day 0	N	6	6	6	16
	Mean	0.67	0.67	0.83	0.31
	SD	0.52	0.52	0.41	0.48
	Median	1.00	1.00	1.00	0.00
	Minimum	0.00	0.00	0.00	0.00
	Maximum	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	0.67	0.17	0.33	0.50	0.67
	SD	0.52	0.41	0.52	0.55	0.52
	Median	1.00	0.00	0.00	0.50	1.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	1	1	1	1	1
Change from Day 0	N	6	6	6	6	6
	Mean	0.50	-0.17	0.17	0.00	0.00
	SD	0.55	0.41	0.75	0.63	0.00
	Median	0.50	0.00	0.00	0.00	0.00
	Minimum	0.00	-1.00	-1.00	-1.00	0.00
	Maximum	1	0	1	1	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				0.30
	SD				0.48
	Median				0.00
	Minimum				0.00
	Maximum				1
Change from Day 0	N	0	0	0	10
	Mean				0.10
	SD				0.32
	Median				0.00
	Minimum				0.00
	Maximum				1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	0.50	0.00	1.00	0.83
	SD	0.55	0.00	0.71	0.41
	Median	0.50	0.00	1.00	1.00
	Minimum	0.00	0.00	0.00	0.00
	Maximum	1	0	2	1
Change from Day 0	N	6	3	5	6
	Mean	-0.17	-0.33	0.20	0.33
	SD	0.41	0.58	0.84	0.52
	Median	0.00	0.00	0.00	0.00
	Minimum	-1.00	-1.00	-1.00	0.00
	Maximum	0	0	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	0.67	0.50	0.17	0.50	0.67
	SD	0.52	0.55	0.41	0.55	0.52
	Median	1.00	0.50	0.00	0.50	1.00
	Minimum	0.00	0.00	0.00	0.00	0.00
	Maximum	1	1	1	1	1
Change from Day 0	N	6	6	6	6	6
	Mean	0.50	0.17	0.00	0.00	0.00
	SD	0.55	0.41	0.63	0.63	0.00
	Median	0.50	0.00	0.00	0.00	0.00
	Minimum	0.00	0.00	-1.00	-1.00	0.00
	Maximum	1	1	1	1	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	0.33		0.60	0.43
	SD	0.52		0.55	0.51
	Median	0.00		1.00	0.00
	Minimum	0.00		0.00	0.00
	Maximum	1		1	1
Change from Day 0	N	6	0	5	14
	Mean	-0.33		-0.20	0.21
	SD	0.52		0.84	0.43
	Median	0.00		0.00	0.00
	Minimum	-1.00		-1.00	0.00
	Maximum	0		1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	0.17		0.60	0.75
	SD	0.41		0.55	0.50
	Median	0.00		1.00	1.00
	Minimum	0.00		0.00	0.00
	Maximum	1		1	1
Change from Day 0	N	6	0	5	4
	Mean	-0.50		-0.20	0.50
	SD	0.55		0.84	0.58
	Median	-0.50		0.00	0.50
	Minimum	-1.00		-1.00	0.00
	Maximum	0		1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.2 - Laboratory Test Results - Hematology: Basophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		0.33	0.00	
	SD		0.58	.	
	Median		0.00	0.00	
	Minimum		0.00	0.00	
	Maximum		1	0	
Change from Day 0	N	0	3	1	0
	Mean		-0.67	-1.00	
	SD		0.58	.	
	Median		-1.00	-1.00	
	Minimum		-1.00	-1.00	
	Maximum		0	-1	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	0.1	0.2	0.2	0.1	0.2
	SD	0.1	0.1	0.1	0.0	0.2
	Median	0.1	0.2	0.1	0.1	0.2
	Minimum	0.1	0.0	0.0	0.1	0.1
	Maximum	0	0	0	0	1
Day 0	N	6	6	6	6	6
	Mean	0.1	0.2	0.2	0.1	0.2
	SD	0.0	0.1	0.3	0.1	0.2
	Median	0.1	0.1	0.2	0.1	0.2
	Minimum	0.1	0.0	0.0	0.0	0.1
	Maximum	0	0	1	0	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	0.2	0.1	0.1	0.1
	SD	0.2	0.1	0.1	0.1
	Median	0.2	0.2	0.1	0.1
	Minimum	0.0	0.0	0.1	0.0
	Maximum	1	0	0	0
Day 0	N	6	6	6	16
	Mean	0.2	0.2	0.2	0.1
	SD	0.1	0.2	0.1	0.1
	Median	0.2	0.2	0.2	0.1
	Minimum	0.1	0.1	0.1	0.0
	Maximum	0	1	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	0.1	0.2	0.2	0.1	0.2
	SD	0.0	0.1	0.2	0.1	0.1
	Median	0.1	0.1	0.2	0.1	0.2
	Minimum	0.1	0.1	0.1	0.0	0.1
	Maximum	0	0	1	0	0
Change from Day 0	N	6	6	6	6	6
	Mean	0.00	0.02	0.02	0.02	-0.05
	SD	0.1	0.1	0.1	0.1	0.1
	Median	0.00	0.00	0.05	0.00	0.00
	Minimum	-0.1	-0.1	-0.2	-0.1	-0.3
	Maximum	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				0.2
	SD				0.1
	Median				0.2
	Minimum				0.0
	Maximum				0
Change from Day 0	N	0	0	0	10
	Mean				0.04
	SD				0.1
	Median				0.00
	Minimum				-0.1
	Maximum				0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	0.3	0.2	0.2	0.1
	SD	0.1	0.2	0.0	0.1
	Median	0.3	0.2	0.2	0.1
	Minimum	0.1	0.0	0.2	0.0
	Maximum	0	0	0	0
Change from Day 0	N	6	3	5	6
	Mean	0.05	-0.07	0.04	-0.03
	SD	0.1	0.2	0.1	0.1
	Median	0.00	-0.10	0.00	0.00
	Minimum	0.0	-0.2	0.0	-0.1
	Maximum	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	0.1	0.2	0.3	0.1	0.3
	SD	0.1	0.1	0.3	0.1	0.2
	Median	0.1	0.2	0.3	0.1	0.2
	Minimum	0.1	0.0	0.0	0.1	0.1
	Maximum	0	0	1	0	1
Change from Day 0	N	6	6	6	6	6
	Mean	0.02	0.05	0.12	0.07	0.02
	SD	0.0	0.1	0.1	0.1	0.0
	Median	0.00	0.05	0.10	0.05	0.00
	Minimum	0.0	0.0	0.0	0.0	0.0
	Maximum	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	0.2		0.2	0.1
	SD	0.1		0.0	0.1
	Median	0.2		0.2	0.1
	Minimum	0.1		0.2	0.0
	Maximum	0		0	0
Change from Day 0	N	6	0	5	14
	Mean	0.02		0.04	0.01
	SD	0.0		0.1	0.1
	Median	0.00		0.00	0.00
	Minimum	0.0		0.0	-0.1
	Maximum	0		0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	0.2		0.2	0.2
	SD	0.1		0.1	0.0
	Median	0.3		0.2	0.2
	Minimum	0.1		0.2	0.2
	Maximum	0		0	0
Change from Day 0	N	6	0	5	4
	Mean	0.03		0.06	0.05
	SD	0.1		0.1	0.1
	Median	0.00		0.10	0.05
	Minimum	0.0		0.0	0.0
	Maximum	0		0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.3 - Laboratory Test Results - Hematology: Eosinophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		0.1	0.1	
	SD		0.2	.	
	Median		0.1	0.1	
	Minimum		0.0	0.1	
	Maximum		0	0	
Change from Day 0	N	0	3	1	0
	Mean		0.00	0.00	
	SD		0.1	.	
	Median		0.00	0.00	
	Minimum		-0.1	0.0	
	Maximum		0	0	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	2.5	2.7	2.7	1.3	4.8
	SD	1.0	2.2	2.4	0.5	4.6
	Median	2.5	2.5	1.5	1.0	3.5
	Minimum	1.0	0.0	1.0	1.0	2.0
	Maximum	4	6	7	2	14
Day 0	N	6	6	6	6	6
	Mean	2.0	2.7	4.0	1.5	4.5
	SD	1.3	2.8	4.3	0.8	3.8
	Median	1.5	2.0	2.5	1.0	3.5
	Minimum	1.0	0.0	0.0	1.0	2.0
	Maximum	4	8	11	3	12

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	4.2	3.2	2.8	1.9
	SD	3.2	2.1	1.5	1.1
	Median	3.5	3.0	2.5	2.0
	Minimum	1.0	1.0	1.0	0.0
	Maximum	10	6	5	4
Day 0	N	6	6	6	16
	Mean	4.2	4.0	3.5	2.4
	SD	2.6	2.9	1.4	0.7
	Median	4.0	3.0	3.5	2.0
	Minimum	1.0	1.0	2.0	1.0
	Maximum	8	8	5	4

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	1.8	2.3	4.2	2.0	3.3
	SD	0.8	1.8	3.6	1.3	1.8
	Median	2.0	1.5	3.0	2.5	2.5
	Minimum	1.0	1.0	1.0	0.0	2.0
	Maximum	3	5	10	3	6
Change from Day 0	N	6	6	6	6	6
	Mean	-0.17	-0.33	0.17	0.50	-1.17
	SD	1.17	1.51	1.17	1.05	2.56
	Median	0.00	0.00	0.00	0.50	0.00
	Minimum	-2.0	-3.0	-1.0	-1.0	-6.0
	Maximum	1	1	2	2	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				2.7
	SD				1.8
	Median				2.0
	Minimum				1.0
	Maximum				6
Change from Day 0	N	0	0	0	10
	Mean				0.30
	SD				1.49
	Median				0.00
	Minimum				-1.0
	Maximum				3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	4.5	3.0	4.0	2.2
	SD	2.3	3.0	1.9	1.0
	Median	4.0	3.0	5.0	2.0
	Minimum	2.0	0.0	2.0	1.0
	Maximum	8	6	6	4
Change from Day 0	N	6	3	5	6
	Mean	0.33	-1.33	0.20	-0.33
	SD	0.82	2.52	0.84	0.82
	Median	0.50	-1.00	0.00	-0.50
	Minimum	-1.0	-4.0	-1.0	-1.0
	Maximum	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	2.0	3.5	5.8	2.0	4.5
	SD	0.6	2.7	6.0	0.6	3.1
	Median	2.0	3.0	4.5	2.0	3.5
	Minimum	1.0	1.0	1.0	1.0	2.0
	Maximum	3	8	17	3	10
Change from Day 0	N	6	6	6	6	6
	Mean	0.00	0.83	1.83	0.50	0.00
	SD	1.10	0.75	2.23	1.05	1.26
	Median	0.00	1.00	1.50	0.50	0.00
	Minimum	-2.0	0.0	0.0	-1.0	-2.0
	Maximum	1	2	6	2	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	4.0		4.4	2.7
	SD	3.0		2.3	1.2
	Median	3.0		5.0	2.5
	Minimum	1.0		2.0	1.0
	Maximum	9		7	5
Change from Day 0	N	6	0	5	14
	Mean	-0.17		0.60	0.21
	SD	0.98		1.14	0.80
	Median	0.00		1.00	0.00
	Minimum	-2.0		-1.0	-1.0
	Maximum	1		2	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	4.7		4.6	3.3
	SD	3.1		2.7	0.5
	Median	5.0		3.0	3.0
	Minimum	1.0		2.0	3.0
	Maximum	10		8	4
Change from Day 0	N	6	0	5	4
	Mean	0.50		0.80	0.50
	SD	1.05		1.64	0.58
	Median	0.50		0.00	0.50
	Minimum	-1.0		-1.0	0.0
	Maximum	2		3	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.4 - Laboratory Test Results - Hematology: Eosinophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		3.0	2.0	
	SD		3.5	.	
	Median		1.0	2.0	
	Minimum		1.0	2.0	
	Maximum		7	2	
Change from Day 0	N	0	3	1	0
	Mean		-0.67	0.00	
	SD		0.58	.	
	Median		-1.00	0.00	
	Minimum		-1.0	0.0	
	Maximum		0	0	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	39.2	40.0	41.2	41.2	40.7
	SD	3.8	4.1	4.3	3.6	4.1
	Median	37.8	41.2	41.8	42.0	40.3
	Minimum	34.6	34.5	34.8	36.4	35.3
	Maximum	45	44	47	46	47
Day 0	N	6	6	6	6	6
	Mean	38.9	38.9	40.8	41.0	40.3
	SD	3.5	3.1	3.0	3.5	4.4
	Median	37.8	39.9	42.1	41.7	39.8
	Minimum	34.7	34.2	36.9	36.7	35.4
	Maximum	44	43	44	46	47

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	41.5	42.7	43.5	41.8
	SD	2.3	3.2	4.0	3.1
	Median	40.9	43.2	45.1	41.7
	Minimum	39.5	37.1	38.0	37.6
	Maximum	45	46	48	48
Day 0	N	6	6	6	16
	Mean	41.2	42.2	42.0	41.1
	SD	2.4	3.2	3.9	3.4
	Median	41.2	42.1	43.6	41.2
	Minimum	38.2	38.0	36.7	35.6
	Maximum	46	47	46	47

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	39.2	39.3	40.8	41.4	40.2
	SD	4.4	3.9	3.7	3.8	4.9
	Median	37.2	40.2	41.5	41.2	38.7
	Minimum	35.6	34.2	36.4	36.8	35.2
	Maximum	45	43	45	47	49
Change from Day 0	N	6	6	6	6	6
	Mean	0.4	0.4	0.0	0.4	-0.1
	SD	1.9	1.4	1.3	1.0	1.5
	Median	1.1	0.4	0.2	0.3	-0.8
	Minimum	-2.8	-1.2	-2.2	-0.8	-1.2
	Maximum	2	2	1	2	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				40.7
	SD				3.3
	Median				41.7
	Minimum				34.8
	Maximum				45
Change from Day 0	N	0	0	0	10
	Mean				0.1
	SD				2.1
	Median				0.8
	Minimum				-3.8
	Maximum				2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	42.8	42.7	44.3	45.8
	SD	2.7	2.3	5.5	2.5
	Median	41.5	43.1	44.2	45.8
	Minimum	40.6	40.3	36.1	42.9
	Maximum	48	45	50	49
Change from Day 0	N	6	3	5	6
	Mean	1.5	1.4	2.5	3.9
	SD	1.5	2.1	2.8	1.4
	Median	1.6	1.9	2.1	3.5
	Minimum	-0.3	-0.9	-0.6	2.1
	Maximum	3	3	6	6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	37.2	38.6	40.1	38.9	38.8
	SD	3.8	3.4	4.0	3.0	4.6
	Median	36.2	38.9	41.3	39.3	38.4
	Minimum	32.3	33.6	33.9	34.1	33.0
	Maximum	42	42	44	42	46
Change from Day 0	N	6	6	6	6	6
	Mean	-1.7	-0.3	-0.7	-2.1	-1.5
	SD	2.3	1.6	1.6	1.3	1.5
	Median	-0.8	-0.4	-0.1	-2.3	-1.3
	Minimum	-6.1	-2.8	-3.1	-4.0	-3.3
	Maximum	0	2	1	-0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	42.1		41.5	41.1
	SD	2.6		6.3	3.3
	Median	41.4		42.7	41.2
	Minimum	39.6		32.3	36.7
	Maximum	47		47	47
Change from Day 0	N	6	0	5	14
	Mean	0.9		-0.2	0.0
	SD	1.3		2.8	1.8
	Median	0.8		0.2	0.6
	Minimum	-1.3		-4.4	-4.2
	Maximum	3		3	3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	40.8		39.8	42.5
	SD	2.5		6.6	2.4
	Median	40.2		40.2	42.0
	Minimum	38.7		31.8	40.3
	Maximum	45		47	46
Change from Day 0	N	6	0	5	4
	Mean	-0.4		-2.0	0.0
	SD	0.9		2.7	1.7
	Median	-0.3		-3.1	-0.6
	Minimum	-1.8		-4.9	-1.2
	Maximum	1		2	3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.5 - Laboratory Test Results - Hematology: Hematocrit (HCT)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		45.7	50.5	
	SD		6.1	.	
	Median		45.9	50.5	
	Minimum		39.6	50.5	
	Maximum		52	51	
Change from Day 0	N	0	3	1	0
	Mean		2.7	7.1	
	SD		1.8	.	
	Median		1.7	7.1	
	Minimum		1.6	7.1	
	Maximum		5	7	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (HgB)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	13.3	14.0	13.9	14.2	14.2
	SD	1.6	2.0	1.6	1.6	1.4
	Median	12.7	14.7	13.9	14.7	14.1
	Minimum	11.6	11.4	11.7	12.2	12.4
	Maximum	16	16	16	16	16
Day 0	N	6	6	6	6	6
	Mean	13.1	13.4	13.9	14.1	14.1
	SD	1.5	1.5	1.2	1.7	1.5
	Median	12.7	13.9	14.3	14.5	14.1
	Minimum	11.3	11.2	12.5	11.9	12.4
	Maximum	15	15	15	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	14.5	14.9	14.7	14.4
	SD	0.8	1.3	1.5	1.1
	Median	14.6	15.1	15.3	14.1
	Minimum	13.6	12.7	12.6	12.9
	Maximum	15	16	16	17
Day 0	N	6	6	6	16
	Mean	14.3	14.3	14.1	14.0
	SD	0.9	1.3	1.4	1.3
	Median	14.2	14.3	14.5	14.1
	Minimum	13.3	12.6	12.2	12.0
	Maximum	16	16	16	17

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	13.1	13.7	14.0	14.4	13.9
	SD	1.8	1.7	1.5	1.8	1.6
	Median	12.3	14.0	14.0	14.8	13.4
	Minimum	11.6	11.5	12.3	12.1	12.5
	Maximum	16	16	16	17	17
Change from Day 0	N	6	6	6	6	6
	Mean	0.1	0.2	0.1	0.3	-0.1
	SD	0.7	0.4	0.5	0.4	0.6
	Median	0.2	0.4	0.1	0.1	-0.2
	Minimum	-1.1	-0.3	-0.8	-0.1	-0.8
	Maximum	0.9	0.9	0.8	1.0	0.6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				13.9
	SD				1.2
	Median				14.3
	Minimum				11.9
	Maximum				16
Change from Day 0	N	0	0	0	10
	Mean				-0.1
	SD				0.8
	Median				0.1
	Minimum				-1.9
	Maximum				0.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	14.9	14.5	14.9	15.3
	SD	0.9	0.9	1.9	0.9
	Median	14.8	14.8	15.1	15.2
	Minimum	13.9	13.5	12.3	14.0
	Maximum	17	15	17	17
Change from Day 0	N	6	3	5	6
	Mean	0.6	0.5	0.9	1.3
	SD	0.6	0.7	0.8	0.4
	Median	0.6	0.5	1.3	1.3
	Minimum	-0.1	-0.2	-0.2	0.8
	Maximum	1.5	1.2	1.5	1.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	12.5	13.4	13.6	13.3	13.4
	SD	1.4	1.6	1.6	1.5	1.4
	Median	12.2	13.7	14.0	14.0	13.3
	Minimum	10.8	11.0	11.2	11.4	11.7
	Maximum	14	15	16	15	16
Change from Day 0	N	6	6	6	6	6
	Mean	-0.5	0.0	-0.3	-0.8	-0.7
	SD	0.8	0.6	0.7	0.5	0.4
	Median	-0.4	0.1	-0.2	-0.8	-0.6
	Minimum	-2.1	-0.9	-1.3	-1.6	-1.3
	Maximum	0.2	0.6	0.7	-0.2	-0.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	14.7		14.0	14.0
	SD	0.9		2.1	1.1
	Median	14.6		14.3	13.9
	Minimum	13.8		11.2	12.4
	Maximum	16		16	16
Change from Day 0	N	6	0	5	14
	Mean	0.4		0.0	-0.1
	SD	0.5		0.9	0.7
	Median	0.6		0.4	0.2
	Minimum	-0.4		-1.3	-1.3
	Maximum	1.0		0.8	0.8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	13.7		13.4	14.2
	SD	0.9		2.4	0.8
	Median	13.5		13.6	14.2
	Minimum	12.8		10.9	13.4
	Maximum	15		16	15
Change from Day 0	N	6	0	5	4
	Mean	-0.6		-0.6	-0.1
	SD	0.3		1.0	0.6
	Median	-0.5		-1.2	0.0
	Minimum	-1.1		-1.6	-0.9
	Maximum	-0.3		0.5	0.5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.6 - Laboratory Test Results - Hematology: Hemoglobin (Hgb)

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		15.6	16.8	
	SD		2.2	.	
	Median		15.5	16.8	
	Minimum		13.4	16.8	
	Maximum		18	17	
Change from Day 0	N	0	3	1	0
	Mean		1.0	2.6	
	SD		0.5	.	
	Median		0.8	2.6	
	Minimum		0.6	2.6	
	Maximum		1.5	2.6	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	1.8	1.7	1.7	2.2	1.8
	SD	0.3	0.6	0.6	0.9	0.4
	Median	1.7	1.6	1.6	2.1	1.8
	Minimum	1.4	1.0	1.2	1.4	1.3
	Maximum	2.3	2.6	2.9	3.7	2.3
Day 0	N	6	6	6	6	6
	Mean	2.0	1.8	1.6	2.1	1.8
	SD	0.5	0.7	0.5	0.7	0.4
	Median	1.9	1.8	1.5	1.8	1.7
	Minimum	1.5	1.0	0.9	1.4	1.4
	Maximum	3.0	2.8	2.4	3.1	2.5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	2.0	1.6	1.5	1.7
	SD	0.5	0.3	0.4	0.3
	Median	2.0	1.5	1.5	1.7
	Minimum	1.3	1.2	1.1	1.2
	Maximum	2.7	2.1	2.0	2.4
Day 0	N	6	6	6	16
	Mean	2.1	1.7	1.7	1.9
	SD	0.5	0.5	0.3	0.5
	Median	2.1	1.7	1.5	1.9
	Minimum	1.2	1.2	1.4	1.1
	Maximum	2.8	2.4	2.3	2.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	1.9	1.8	1.8	2.1	2.1
	SD	0.3	0.6	0.4	0.5	0.6
	Median	1.7	1.7	1.8	2.1	2.0
	Minimum	1.6	1.3	1.3	1.6	1.5
	Maximum	2.4	2.9	2.3	3.0	2.9
Change from Day 0	N	6	6	6	6	6
	Mean	-0.12	0.03	0.23	0.08	0.28
	SD	0.47	0.28	0.23	0.33	0.16
	Median	-0.05	0.05	0.25	0.05	0.30
	Minimum	-0.8	-0.3	-0.1	-0.3	0.1
	Maximum	0.5	0.5	0.5	0.5	0.5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				1.9
	SD				0.4
	Median				1.8
	Minimum				1.4
	Maximum				2.5
Change from Day 0	N	0	0	0	10
	Mean				0.16
	SD				0.30
	Median				0.20
	Minimum				-0.3
	Maximum				0.6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	2.3	1.8	1.6	2.3
	SD	0.6	0.0	0.3	0.3
	Median	2.4	1.8	1.5	2.4
	Minimum	1.4	1.8	1.3	1.7
	Maximum	3.0	1.8	2.1	2.6
Change from Day 0	N	6	3	5	6
	Mean	0.28	0.00	-0.10	0.02
	SD	0.28	0.26	0.26	0.33
	Median	0.20	0.10	-0.20	0.15
	Minimum	-0.1	-0.3	-0.4	-0.6
	Maximum	0.7	0.2	0.3	0.3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	1.8	1.9	1.7	2.0	2.4
	SD	0.4	0.6	0.4	0.6	0.9
	Median	1.9	1.8	1.6	1.9	2.2
	Minimum	1.4	1.2	1.1	1.2	1.6
	Maximum	2.2	2.9	2.4	2.9	3.7
Change from Day 0	N	6	6	6	6	6
	Mean	-0.17	0.13	0.08	-0.10	0.60
	SD	0.37	0.27	0.28	0.24	0.53
	Median	-0.10	0.10	0.10	-0.20	0.60
	Minimum	-0.8	-0.2	-0.3	-0.4	0.0
	Maximum	0.3	0.6	0.5	0.2	1.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	2.2		1.7	1.9
	SD	0.5		0.5	0.5
	Median	2.4		1.3	1.9
	Minimum	1.4		1.3	1.2
	Maximum	2.8		2.5	2.6
Change from Day 0	N	6	0	5	14
	Mean	0.18		-0.06	0.01
	SD	0.21		0.42	0.38
	Median	0.20		-0.20	-0.10
	Minimum	-0.1		-0.6	-0.4
	Maximum	0.5		0.5	0.8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	2.2		1.4	2.4
	SD	0.7		0.4	0.6
	Median	2.2		1.3	2.4
	Minimum	1.3		1.2	1.6
	Maximum	3.4		2.1	3.0
Change from Day 0	N	6	0	5	4
	Mean	0.17		-0.28	0.00
	SD	0.27		0.25	0.34
	Median	0.10		-0.20	0.00
	Minimum	-0.2		-0.7	-0.4
	Maximum	0.6		-0.1	0.4

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.7 - Laboratory Test Results - Hematology: Lymphocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		1.8	1.8	
	SD		1.0	.	
	Median		1.4	1.8	
	Minimum		1.0	1.8	
	Maximum		2.9	1.8	
Change from Day 0	N	0	3	1	0
	Mean		0.13	0.30	
	SD		0.35	.	
	Median		0.10	0.30	
	Minimum		-0.2	0.3	
	Maximum		0.5	0.3	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	36.5	33.5	35.5	34.8	36.7
	SD	7.7	11.6	11.4	15.6	8.8
	Median	34.0	27.5	35.0	33.0	38.0
	Minimum	29	25	20	16	22
	Maximum	49	54	54	53	48
Day 0	N	6	6	6	6	6
	Mean	35.8	30.7	32.3	36.8	37.2
	SD	8.2	13.6	5.6	14.0	6.7
	Median	33.0	29.0	32.0	34.5	40.0
	Minimum	28	13	25	23	25
	Maximum	46	48	41	59	43

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	40.8	36.3	29.8	34.6
	SD	9.6	10.4	8.0	10.6
	Median	40.0	35.0	31.0	33.5
	Minimum	28	25	15	23
	Maximum	56	50	38	65
Day 0	N	6	6	6	16
	Mean	41.0	37.0	32.3	35.9
	SD	9.6	8.3	6.5	10.2
	Median	38.5	33.0	34.0	33.0
	Minimum	29	29	22	21
	Maximum	58	49	38	57

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	36.5	32.0	36.2	38.2	39.0
	SD	10.7	12.9	7.4	13.4	10.0
	Median	37.5	31.5	36.0	36.5	40.0
	Minimum	23	14	25	26	24
	Maximum	53	54	47	62	50
Change from Day 0	N	6	6	6	6	6
	Mean	0.7	1.3	3.8	1.3	1.8
	SD	6.8	6.3	6.8	6.3	4.9
	Median	0.0	3.5	4.5	2.5	1.5
	Minimum	-7	-10	-7	-7	-5
	Maximum	10	6	12	11	7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				38.4
	SD				8.4
	Median				37.5
	Minimum				27
	Maximum				54
Change from Day 0	N	0	0	0	10
	Mean				4.9
	SD				5.8
	Median				5.0
	Minimum				-6
	Maximum				13

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	42.2	27.0	31.6	40.7
	SD	8.5	3.5	7.3	13.0
	Median	44.0	29.0	33.0	35.5
	Minimum	27	23	21	30
	Maximum	50	29	39	63
Change from Day 0	N	6	3	5	6
	Mean	1.2	-4.7	-1.6	0.8
	SD	6.9	5.0	1.9	3.2
	Median	-0.5	-4.0	-1.0	1.0
	Minimum	-8	-10	-4	-4
	Maximum	11	0	1	6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	37.7	34.7	33.0	37.8	41.3
	SD	7.8	11.8	8.9	10.9	8.9
	Median	38.5	33.0	35.0	37.0	42.0
	Minimum	28	21	19	24	28
	Maximum	49	50	44	56	51
Change from Day 0	N	6	6	6	6	6
	Mean	1.8	4.0	0.7	1.0	4.2
	SD	6.2	3.9	8.8	11.4	5.3
	Median	1.0	2.5	2.5	2.0	4.5
	Minimum	-5	0	-15	-20	-5
	Maximum	9	11	9	12	10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	43.5		32.4	36.1
	SD	9.0		6.1	8.4
	Median	45.0		35.0	34.5
	Minimum	29		24	21
	Maximum	56		38	53
Change from Day 0	N	6	0	5	14
	Mean	2.5		-0.8	1.3
	SD	4.4		4.8	6.5
	Median	0.5		0.0	1.0
	Minimum	-2		-7	-11
	Maximum	9		6	15

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	42.7		26.0	37.8
	SD	9.1		6.7	6.1
	Median	41.5		29.0	39.5
	Minimum	30		14	29
	Maximum	58		30	43
Change from Day 0	N	6	0	5	4
	Mean	1.7		-7.2	-0.3
	SD	3.7		2.5	3.6
	Median	2.0		-8.0	0.5
	Minimum	-4		-9	-5
	Maximum	7		-3	3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.8 - Laboratory Test Results - Hematology: Lymphocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		32.0	36.0	
	SD		9.6	.	
	Median		28.0	36.0	
	Minimum		25	36	
	Maximum		43	36	
Change from Day 0	N	0	3	1	0
	Mean		-10.3	8.0	
	SD		9.3	.	
	Median		-6.0	8.0	
	Minimum		-21	8	
	Maximum		-4	8	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	0.5	0.4	0.4	0.6	0.4
	SD	0.1	0.1	0.1	0.1	0.2
	Median	0.4	0.4	0.4	0.6	0.5
	Minimum	0.3	0.3	0.3	0.4	0.2
	Maximum	1	1	1	1	1
Day 0	N	6	6	6	6	6
	Mean	0.5	0.5	0.4	0.5	0.5
	SD	0.2	0.2	0.1	0.1	0.2
	Median	0.4	0.5	0.4	0.5	0.5
	Minimum	0.3	0.3	0.3	0.3	0.2
	Maximum	1	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	0.5	0.3	0.4	0.4
	SD	0.1	0.1	0.1	0.1
	Median	0.4	0.3	0.5	0.5
	Minimum	0.3	0.2	0.3	0.2
	Maximum	1	1	1	1
Day 0	N	6	6	6	16
	Mean	0.5	0.3	0.5	0.5
	SD	0.1	0.1	0.1	0.1
	Median	0.5	0.3	0.4	0.5
	Minimum	0.4	0.3	0.3	0.3
	Maximum	1	0	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	0.5	0.5	0.4	0.4	0.4
	SD	0.3	0.2	0.0	0.1	0.2
	Median	0.4	0.5	0.4	0.4	0.5
	Minimum	0.3	0.4	0.3	0.3	0.2
	Maximum	1	1	0	1	1
Change from Day 0	N	6	6	6	6	6
	Mean	0.00	0.00	0.02	-0.08	-0.03
	SD	0.1	0.1	0.1	0.1	0.1
	Median	0.0	0.0	0.0	-0.1	0.0
	Minimum	-0.1	-0.1	-0.1	-0.2	-0.3
	Maximum	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				0.5
	SD				0.2
	Median				0.6
	Minimum				0.2
	Maximum				1
Change from Day 0	N	0	0	0	10
	Mean				-0.01
	SD				0.1
	Median				0.0
	Minimum				-0.2
	Maximum				0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	0.5	0.4	0.4	0.6
	SD	0.1	0.1	0.2	0.2
	Median	0.5	0.4	0.4	0.6
	Minimum	0.4	0.4	0.3	0.3
	Maximum	1	1	1	1
Change from Day 0	N	6	3	5	6
	Mean	0.02	0.07	-0.02	0.05
	SD	0.1	0.1	0.1	0.2
	Median	0.0	0.1	0.0	0.1
	Minimum	-0.1	0.0	-0.1	-0.1
	Maximum	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	0.5	0.5	0.5	0.5	0.6
	SD	0.1	0.1	0.1	0.1	0.3
	Median	0.5	0.5	0.5	0.5	0.6
	Minimum	0.3	0.3	0.3	0.4	0.2
	Maximum	1	1	1	1	1
Change from Day 0	N	6	6	6	6	6
	Mean	0.00	-0.03	0.08	0.00	0.08
	SD	0.1	0.2	0.1	0.1	0.2
	Median	0.1	-0.1	0.1	0.0	0.1
	Minimum	-0.2	-0.2	0.0	-0.2	-0.1
	Maximum	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	0.5		0.5	0.5
	SD	0.1		0.2	0.2
	Median	0.4		0.5	0.6
	Minimum	0.3		0.3	0.3
	Maximum	1		1	1
Change from Day 0	N	6	0	5	14
	Mean	-0.03		0.02	0.02
	SD	0.1		0.2	0.1
	Median	-0.1		-0.1	0.0
	Minimum	-0.1		-0.1	-0.2
	Maximum	0		0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	0.5		0.5	0.5
	SD	0.1		0.2	0.1
	Median	0.5		0.4	0.5
	Minimum	0.4		0.3	0.4
	Maximum	1		1	1
Change from Day 0	N	6	0	5	4
	Mean	0.02		0.04	-0.03
	SD	0.1		0.2	0.1
	Median	0.0		0.0	0.0
	Minimum	-0.2		-0.2	-0.2
	Maximum	0		0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.9 - Laboratory Test Results - Hematology: Monocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		0.3	0.4	
	SD		0.0	.	
	Median		0.3	0.4	
	Minimum		0.3	0.4	
	Maximum		0	0	
Change from Day 0	N	0	3	1	0
	Mean		0.00	0.00	
	SD		0.0	.	
	Median		0.0	0.0	
	Minimum		0.0	0.0	
	Maximum		0	0	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	9.0	7.8	8.2	8.2	8.7
	SD	1.1	1.2	1.5	1.2	2.7
	Median	9.0	7.5	8.5	8.0	9.5
	Minimum	8	7	6	7	4
	Maximum	11	10	10	10	11
Day 0	N	6	6	6	6	6
	Mean	8.3	8.8	8.2	8.3	9.0
	SD	1.9	3.2	1.6	0.8	2.9
	Median	8.0	8.0	7.5	8.5	10.0
	Minimum	6	6	7	7	5
	Maximum	11	15	11	9	12

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	9.0	7.3	9.0	8.8
	SD	3.2	2.3	2.3	2.4
	Median	8.5	6.5	9.5	8.0
	Minimum	6	5	5	5
	Maximum	15	11	11	15
Day 0	N	6	6	6	16
	Mean	9.8	7.2	8.7	9.3
	SD	2.2	1.3	1.8	2.2
	Median	9.5	7.0	8.5	9.5
	Minimum	8	6	6	6
	Maximum	14	9	11	14

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	8.8	8.3	8.0	7.5	8.0
	SD	2.3	2.0	0.6	0.5	2.5
	Median	10.0	8.0	8.0	7.5	8.5
	Minimum	5	6	7	7	5
	Maximum	11	11	9	8	11
Change from Day 0	N	6	6	6	6	6
	Mean	0.50	-0.50	-0.17	-0.83	-1.00
	SD	1.22	2.59	1.72	0.75	1.10
	Median	0.00	0.50	0.00	-1.00	-1.00
	Minimum	-1.0	-5.0	-3.0	-2.0	-3.0
	Maximum	2.0	2.0	2.0	0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				9.4
	SD				2.5
	Median				10.0
	Minimum				6
	Maximum				14
Change from Day 0	N	0	0	0	10
	Mean				-0.30
	SD				1.42
	Median				-0.50
	Minimum				-3.0
	Maximum				2.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	9.0	6.7	8.2	8.7
	SD	2.0	0.6	1.5	1.5
	Median	9.0	7.0	8.0	9.0
	Minimum	7	6	6	6
	Maximum	12	7	10	10
Change from Day 0	N	6	3	5	6
	Mean	-0.83	0.00	-0.60	0.17
	SD	1.60	1.00	1.95	1.72
	Median	-1.50	0.00	0.00	0.00
	Minimum	-2.0	-1.0	-3.0	-2.0
	Maximum	2.0	1.0	2.0	3.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	9.7	8.8	8.5	9.3	9.2
	SD	1.5	2.3	1.6	1.0	2.1
	Median	9.0	9.0	8.0	9.0	10.0
	Minimum	8	5	7	8	6
	Maximum	12	12	11	11	11
Change from Day 0	N	6	6	6	6	6
	Mean	1.33	0.00	0.33	1.00	0.17
	SD	1.03	1.79	0.52	0.63	1.60
	Median	1.00	0.50	0.00	1.00	0.00
	Minimum	0.0	-3.0	0.0	0.0	-2.0
	Maximum	3.0	2.0	1.0	2.0	2.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	8.7		9.2	9.7
	SD	2.3		1.1	3.0
	Median	8.0		9.0	10.0
	Minimum	6		8	6
	Maximum	13		11	15
Change from Day 0	N	6	0	5	14
	Mean	-1.17		0.40	0.57
	SD	0.75		1.82	2.98
	Median	-1.00		1.00	0.00
	Minimum	-2.0		-2.0	-4.0
	Maximum	0.0		2.0	8.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	9.8		8.4	7.5
	SD	1.0		2.7	1.3
	Median	9.5		8.0	7.5
	Minimum	9		5	6
	Maximum	11		12	9
Change from Day 0	N	6	0	5	4
	Mean	0.00		-0.40	-0.25
	SD	2.19		3.65	1.26
	Median	1.00		1.00	0.00
	Minimum	-4.0		-6.0	-2.0
	Maximum	2.0		3.0	1.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.10 - Laboratory Test Results - Hematology: Monocytes/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		6.0	8.0	
	SD		1.0	.	
	Median		6.0	8.0	
	Minimum		5	8	
	Maximum		7	8	
Change from Day 0	N	0	3	1	0
	Mean		-1.67	0.00	
	SD		0.58	.	
	Median		-2.00	0.00	
	Minimum		-2.0	0.0	
	Maximum		-1.0	0.0	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	2.6	2.8	2.6	3.9	2.5
	SD	1.1	0.6	0.9	2.0	0.8
	Median	2.6	2.8	2.5	3.3	2.6
	Minimum	1.2	1.8	1.9	1.7	1.2
	Maximum	4.6	3.5	4.2	6.8	3.6
Day 0	N	6	6	6	6	6
	Mean	3.3	3.8	2.6	3.2	2.4
	SD	1.7	2.1	0.7	1.3	0.7
	Median	3.1	3.5	2.8	3.2	2.3
	Minimum	1.4	1.2	1.6	1.6	1.7
	Maximum	6.2	7.0	3.4	5.0	3.6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	2.3	2.5	3.3	2.9
	SD	1.0	1.1	1.9	1.0
	Median	2.2	2.1	2.8	3.0
	Minimum	1.3	1.4	1.9	0.8
	Maximum	4.2	3.9	7.1	4.2
Day 0	N	6	6	6	16
	Mean	2.3	2.6	3.0	3.0
	SD	0.8	1.0	0.8	1.1
	Median	2.2	2.6	3.0	3.0
	Minimum	1.3	1.0	1.9	1.3
	Maximum	3.2	3.7	4.3	5.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	3.1	3.6	2.6	3.1	2.7
	SD	1.8	1.6	0.6	1.1	0.8
	Median	2.6	3.6	2.6	3.4	2.6
	Minimum	1.1	1.9	1.7	1.3	1.8
	Maximum	6.1	6.3	3.4	4.0	4.0
Change from Day 0	N	6	6	6	6	6
	Mean	-0.13	-0.28	-0.08	-0.12	0.28
	SD	0.6	0.8	0.8	0.8	0.5
	Median	-0.10	-0.30	-0.10	0.05	0.20
	Minimum	-1.1	-1.4	-1.4	-1.5	-0.2
	Maximum	0.8	0.7	0.7	0.8	1.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				2.6
	SD				1.1
	Median				2.5
	Minimum				1.3
	Maximum				4.6
Change from Day 0	N	0	0	0	10
	Mean				-0.39
	SD				0.7
	Median				-0.30
	Minimum				-1.7
	Maximum				0.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	2.5	4.4	3.1	3.0
	SD	0.7	1.0	1.4	1.3
	Median	2.3	4.0	2.8	3.2
	Minimum	1.8	3.6	1.8	1.1
	Maximum	3.5	5.5	5.3	4.4
Change from Day 0	N	6	3	5	6
	Mean	0.22	1.10	0.16	0.08
	SD	0.6	1.5	0.6	0.4
	Median	0.45	0.30	0.00	0.10
	Minimum	-0.7	0.2	-0.5	-0.6
	Maximum	1.0	2.8	1.0	0.6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	2.6	3.1	2.9	2.7	2.7
	SD	1.1	1.2	1.5	0.9	1.1
	Median	2.3	3.4	2.2	3.0	2.4
	Minimum	1.7	1.1	1.7	1.3	1.7
	Maximum	4.7	4.6	5.6	3.6	4.7
Change from Day 0	N	6	6	6	6	6
	Mean	-0.72	-0.75	0.23	-0.47	0.27
	SD	0.8	1.1	1.3	1.4	0.6
	Median	-0.80	-0.30	0.15	-0.65	0.10
	Minimum	-1.6	-2.4	-1.4	-2.2	-0.6
	Maximum	0.3	0.5	2.5	2.0	1.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	2.3		2.9	2.8
	SD	0.7		1.1	1.1
	Median	2.1		3.3	2.6
	Minimum	1.5		1.6	1.7
	Maximum	3.5		4.1	5.8
Change from Day 0	N	6	0	5	14
	Mean	0.00		-0.04	-0.20
	SD	0.5		0.6	0.9
	Median	0.20		-0.10	-0.05
	Minimum	-0.8		-0.8	-3.1
	Maximum	0.5		0.7	0.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	2.2		3.6	3.1
	SD	0.4		2.0	0.4
	Median	2.2		3.1	3.1
	Minimum	1.6		2.2	2.7
	Maximum	2.8		7.0	3.6
Change from Day 0	N	6	0	5	4
	Mean	-0.10		0.74	-0.03
	SD	0.5		1.1	0.3
	Median	-0.00		0.30	-0.05
	Minimum	-0.9		-0.2	-0.3
	Maximum	0.3		2.7	0.3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.11 - Laboratory Test Results - Hematology: Neutrophils

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		3.0	2.7	
	SD		0.5	.	
	Median		3.2	2.7	
	Minimum		2.4	2.7	
	Maximum		3.3	2.7	
Change from Day 0	N	0	3	1	0
	Mean		1.13	-0.60	
	SD		0.3	.	
	Median		1.20	-0.60	
	Minimum		0.8	-0.6	
	Maximum		1.4	-0.6	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	51.3	55.3	53.7	55.5	49.3
	SD	8.6	10.6	11.5	16.5	13.4
	Median	54.0	58.5	54.5	58.0	49.0
	Minimum	36	37	36	35	26
	Maximum	59	65	72	75	64
Day 0	N	6	6	6	6	6
	Mean	53.5	57.3	55.2	53.3	48.7
	SD	10.1	16.3	7.0	14.4	9.7
	Median	55.5	62.0	55.0	56.5	50.0
	Minimum	40	33	46	30	33
	Maximum	65	74	67	67	62

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	45.3	53.2	58.2	54.2
	SD	9.8	11.9	11.6	10.2
	Median	49.5	53.5	56.0	55.0
	Minimum	32	38	46	25
	Maximum	55	67	80	67
Day 0	N	6	6	6	16
	Mean	44.8	51.3	55.0	52.2
	SD	10.3	10.4	7.5	10.2
	Median	49.5	54.5	54.0	53.5
	Minimum	27	35	47	31
	Maximum	53	63	65	70

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	52.7	56.8	51.3	52.2	49.2
	SD	11.6	12.1	10.5	13.9	11.3
	Median	51.0	60.5	52.5	54.5	49.0
	Minimum	35	36	34	27	33
	Maximum	67	70	64	65	65
Change from Day 0	N	6	6	6	6	6
	Mean	-0.8	-0.5	-3.8	-1.2	0.5
	SD	7.0	9.3	6.2	6.9	2.7
	Median	1.5	-5.0	-4.5	-2.5	0.5
	Minimum	-13	-7	-12	-11	-3
	Maximum	6	17	5	9	4

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				49.0
	SD				7.7
	Median				49.0
	Minimum				39
	Maximum				59
Change from Day 0	N	0	0	0	10
	Mean				-5.2
	SD				7.3
	Median				-4.5
	Minimum				-16
	Maximum				7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	44.0	63.7	55.4	48.0
	SD	8.7	6.7	9.0	12.0
	Median	42.0	62.0	55.0	51.5
	Minimum	34	58	47	27
	Maximum	59	71	68	58
Change from Day 0	N	6	3	5	6
	Mean	-0.8	6.3	1.8	-0.8
	SD	7.3	8.7	2.2	1.7
	Median	0.0	4.0	3.0	-0.5
	Minimum	-12	-1	-1	-4
	Maximum	7	16	4	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	49.8	52.2	52.3	50.2	44.3
	SD	6.9	14.0	13.0	11.0	11.0
	Median	50.0	56.5	54.0	50.0	44.5
	Minimum	41	32	31	32	28
	Maximum	60	67	67	64	57
Change from Day 0	N	6	6	6	6	6
	Mean	-3.7	-5.2	-2.8	-3.2	-4.3
	SD	7.6	4.1	9.4	11.6	3.6
	Median	-1.5	-4.5	-3.0	-4.0	-5.0
	Minimum	-13	-13	-15	-15	-8
	Maximum	4	-1	12	18	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	43.5		53.0	51.1
	SD	8.1		7.5	6.8
	Median	43.5		49.0	51.0
	Minimum	32		45	39
	Maximum	55		62	65
Change from Day 0	N	6	0	5	14
	Mean	-1.3		-0.6	-2.2
	SD	5.2		4.0	7.4
	Median	0.0		-2.0	-1.5
	Minimum	-9		-5	-19
	Maximum	5		5	10

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	42.3		60.0	50.8
	SD	9.0		10.6	6.2
	Median	43.0		54.0	48.0
	Minimum	27		53	47
	Maximum	55		78	60
Change from Day 0	N	6	0	5	4
	Mean	-2.5		6.4	-0.3
	SD	4.8		4.0	4.2
	Median	-2.5		5.0	0.5
	Minimum	-9		3	-6
	Maximum	3		13	4

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.12 - Laboratory Test Results - Hematology: Neutrophils/Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		58.3	55.0	
	SD		7.4	.	
	Median		61.0	55.0	
	Minimum		50	55	
	Maximum		64	55	
Change from Day 0	N	0	3	1	0
	Mean		13.0	-7.0	
	SD		11.3	.	
	Median		7.0	-7.0	
	Minimum		6	-7	
	Maximum		26	-7	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	258.3	254.0	250.7	304.2	259.3
	SD	95.1	31.5	45.9	59.3	30.5
	Median	245.5	262.0	262.0	280.0	241.5
	Minimum	144	195	181	269	238
	Maximum	424	279	315	424	303
Day 0	N	6	6	6	6	6
	Mean	273.2	257.2	235.5	309.2	253.7
	SD	108.6	34.1	60.3	85.3	18.6
	Median	248.0	263.0	234.0	277.5	253.5
	Minimum	148	214	160	241	226
	Maximum	464	302	309	473	276

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	237.2	245.3	241.0	263.0
	SD	18.9	47.8	58.4	52.4
	Median	239.5	235.5	233.5	263.0
	Minimum	206	183	180	182
	Maximum	256	319	350	343
Day 0	N	6	6	6	16
	Mean	237.7	233.3	237.2	244.4
	SD	26.2	45.1	54.4	48.0
	Median	245.5	234.5	224.0	246.0
	Minimum	202	174	191	144
	Maximum	265	293	336	324

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	277.5	252.0	233.8	306.3	254.2
	SD	90.5	25.7	60.6	93.2	25.0
	Median	266.5	255.5	230.5	280.0	254.5
	Minimum	162	212	150	241	226
	Maximum	423	282	315	490	288
Change from Day 0	N	6	6	6	6	6
	Mean	4.3	-5.2	-1.7	-2.8	0.5
	SD	26.4	16.4	12.2	16.0	14.8
	Median	8.0	-5.5	-1.5	-2.5	6.0
	Minimum	-41	-29	-18	-22	-18
	Maximum	37	20	11	17	13

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				250.9
	SD				39.6
	Median				250.5
	Minimum				196
	Maximum				315
Change from Day 0	N	0	0	0	10
	Mean				-5.4
	SD				10.2
	Median				-5.0
	Minimum				-25
	Maximum				9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	235.0	234.7	231.4	230.8
	SD	21.5	67.7	62.1	53.1
	Median	245.0	241.0	212.0	227.0
	Minimum	203	164	186	166
	Maximum	253	299	340	324
Change from Day 0	N	6	3	5	6
	Mean	-2.7	-0.7	-1.8	6.3
	SD	6.5	8.3	7.4	15.3
	Median	-0.5	2.0	-5.0	3.0
	Minimum	-14	-10	-8	-15
	Maximum	4	6	8	26

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	257.7	264.3	240.2	295.2	258.7
	SD	88.8	22.7	62.5	96.6	40.6
	Median	244.5	272.5	247.0	257.0	249.0
	Minimum	151	225	161	249	214
	Maximum	414	285	319	492	315
Change from Day 0	N	6	6	6	6	6
	Mean	-15.5	7.2	4.7	-14.0	5.0
	SD	28.3	34.1	13.6	29.9	29.8
	Median	-19.0	10.5	-1.5	-14.5	4.0
	Minimum	-50	-51	-5	-61	-31
	Maximum	26	56	30	19	39

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	242.5		228.8	258.5
	SD	31.0		56.3	47.9
	Median	255.0		228.0	241.0
	Minimum	195		178	187
	Maximum	269		319	351
Change from Day 0	N	6	0	5	14
	Mean	4.8		-4.4	11.0
	SD	6.6		12.2	22.3
	Median	6.0		-6.0	12.0
	Minimum	-7		-17	-19
	Maximum	11		14	43

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	226.3		250.0	249.5
	SD	27.2		60.0	71.1
	Median	240.0		230.0	255.0
	Minimum	191		186	161
	Maximum	249		343	327
Change from Day 0	N	6	0	5	4
	Mean	-11.3		16.8	24.0
	SD	11.2		18.9	11.0
	Median	-11.5		10.0	23.0
	Minimum	-27		-5	13
	Maximum	6		42	37

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.13 - Laboratory Test Results - Hematology: Platelets

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		244.3	270.0	
	SD		50.2	.	
	Median		254.0	270.0	
	Minimum		190	270	
	Maximum		289	270	
Change from Day 0	N	0	3	1	0
	Mean		13.0	13.0	
	SD		14.2	.	
	Median		18.0	13.0	
	Minimum		-3	13	
	Maximum		24	13	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	4.8	4.7	4.8	5.2	4.8
	SD	0.3	0.5	0.5	0.5	0.6
	Median	4.9	4.9	4.9	5.2	4.9
	Minimum	4	4	4	5	4
	Maximum	5	5	5	6	5
Day 0	N	6	6	6	6	6
	Mean	4.7	4.6	4.7	5.2	4.7
	SD	0.2	0.4	0.4	0.5	0.6
	Median	4.8	4.8	4.9	5.2	4.8
	Minimum	4	4	4	5	4
	Maximum	5	5	5	6	6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	4.8	5.0	4.9	4.8
	SD	0.3	0.4	0.4	0.4
	Median	4.8	4.9	4.9	4.6
	Minimum	4	4	4	4
	Maximum	5	6	5	6
Day 0	N	6	6	6	16
	Mean	4.8	4.8	4.7	4.7
	SD	0.3	0.4	0.3	0.4
	Median	4.8	4.7	4.7	4.5
	Minimum	4	4	4	4
	Maximum	5	5	5	5

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	4.8	4.7	4.7	5.3	4.7
	SD	0.3	0.4	0.5	0.6	0.6
	Median	4.8	4.6	4.9	5.2	4.6
	Minimum	4	4	4	5	4
	Maximum	5	5	5	6	5
Change from Day 0	N	6	6	6	6	6
	Mean	0.08	0.06	0.02	0.07	-0.04
	SD	0.22	0.17	0.16	0.14	0.19
	Median	0.14	0.07	0.05	0.05	-0.10
	Minimum	-0.31	-0.14	-0.26	-0.08	-0.21
	Maximum	0.30	0.29	0.20	0.31	0.23

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				4.6
	SD				0.5
	Median				4.5
	Minimum				4
	Maximum				5
Change from Day 0	N	0	0	0	10
	Mean				-0.01
	SD				0.23
	Median				0.06
	Minimum				-0.45
	Maximum				0.25

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	4.9	4.8	5.1	5.1
	SD	0.3	0.4	0.6	0.3
	Median	4.9	5.0	5.1	5.1
	Minimum	5	4	4	5
	Maximum	6	5	6	6
Change from Day 0	N	6	3	5	6
	Mean	0.15	0.16	0.33	0.41
	SD	0.18	0.22	0.31	0.12
	Median	0.14	0.18	0.33	0.39
	Minimum	-0.07	-0.07	-0.04	0.30
	Maximum	0.42	0.37	0.65	0.58

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	4.6	4.6	4.6	4.9	4.5
	SD	0.3	0.4	0.5	0.5	0.7
	Median	4.6	4.8	4.8	5.0	4.6
	Minimum	4	4	4	4	4
	Maximum	5	5	5	6	5
Change from Day 0	N	6	6	6	6	6
	Mean	-0.14	-0.02	-0.10	-0.29	-0.21
	SD	0.28	0.18	0.20	0.17	0.14
	Median	-0.06	-0.02	-0.06	-0.28	-0.17
	Minimum	-0.71	-0.30	-0.41	-0.56	-0.39
	Maximum	0.06	0.19	0.19	-0.12	-0.06

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	4.9		4.8	4.7
	SD	0.3		0.7	0.4
	Median	4.8		4.7	4.6
	Minimum	5		4	4
	Maximum	5		5	5
Change from Day 0	N	6	0	5	14
	Mean	0.11		0.00	-0.00
	SD	0.17		0.34	0.20
	Median	0.10		0.12	0.06
	Minimum	-0.15		-0.52	-0.42
	Maximum	0.32		0.36	0.32

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	4.6		4.5	4.8
	SD	0.3		0.7	0.3
	Median	4.5		4.4	4.8
	Minimum	4		4	4
	Maximum	5		5	5
Change from Day 0	N	6	0	5	4
	Mean	-0.20		-0.22	-0.05
	SD	0.08		0.36	0.13
	Median	-0.18		-0.43	-0.09
	Minimum	-0.34		-0.56	-0.17
	Maximum	-0.12		0.21	0.14

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.2.14 - Laboratory Test Results - Hematology: Erythrocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		5.2	5.4	
	SD		0.5	.	
	Median		5.4	5.4	
	Minimum		5	5	
	Maximum		6	5	
Change from Day 0	N	0	3	1	0
	Mean		0.28	0.80	
	SD		0.12	.	
	Median		0.25	0.80	
	Minimum		0.18	0.80	
	Maximum		0.42	0.80	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	5.0	5.1	4.9	6.8	5.1
	SD	1.6	0.8	0.8	1.8	0.7
	Median	4.6	5.1	4.9	6.4	5.3
	Minimum	3	4	4	5	4
	Maximum	8	6	6	9	6
Day 0	N	6	6	6	6	6
	Mean	5.9	6.3	4.8	5.8	5.0
	SD	2.3	2.1	1.3	1.1	0.9
	Median	5.2	6.0	4.8	5.8	4.8
	Minimum	3	4	3	4	4
	Maximum	10	9	7	7	6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	5.0	4.5	5.4	5.2
	SD	1.3	1.1	1.9	1.1
	Median	4.5	4.3	5.0	5.3
	Minimum	4	3	4	3
	Maximum	8	6	9	7
Day 0	N	6	6	6	16
	Mean	5.0	4.8	5.4	5.6
	SD	0.9	1.3	0.9	1.2
	Median	4.8	4.9	5.2	5.5
	Minimum	4	3	4	4
	Maximum	6	6	7	8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	5.7	6.1	5.0	5.8	5.5
	SD	2.3	1.8	0.6	0.7	0.8
	Median	5.3	5.9	5.1	6.1	5.6
	Minimum	3	4	4	5	4
	Maximum	10	9	6	6	6
Change from Day 0	N	6	6	6	6	6
	Mean	-0.2	-0.2	0.1	-0.0	0.5
	SD	0.7	0.8	1.1	0.7	0.5
	Median	-0.45	-0.30	0.20	-0.05	0.40
	Minimum	-1	-2	-2	-1	-0
	Maximum	1	1	1	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				5.2
	SD				1.5
	Median				5.2
	Minimum				3
	Maximum				8
Change from Day 0	N	0	0	0	10
	Mean				-0.2
	SD				0.8
	Median				-0.30
	Minimum				-2
	Maximum				2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	5.6	6.8	5.3	6.0
	SD	1.0	0.9	1.8	1.5
	Median	5.3	6.4	4.7	6.0
	Minimum	4	6	4	4
	Maximum	7	8	8	8
Change from Day 0	N	6	3	5	6
	Mean	0.5	1.1	-0.0	0.1
	SD	0.6	1.6	0.9	0.8
	Median	0.50	0.50	-0.10	0.20
	Minimum	-0	-0	-1	-1
	Maximum	1	3	1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	5.1	5.7	5.3	5.2	6.0
	SD	1.6	1.3	1.8	1.2	1.7
	Median	4.7	5.7	5.1	5.3	6.1
	Minimum	4	4	3	4	4
	Maximum	8	8	8	7	8
Change from Day 0	N	6	6	6	6	6
	Mean	-0.8	-0.6	0.5	-0.6	1.0
	SD	1.0	1.3	1.4	1.5	1.1
	Median	-0.70	-0.10	0.30	-0.90	1.20
	Minimum	-2	-2	-1	-2	-1
	Maximum	0	1	3	2	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	5.2		5.3	5.4
	SD	1.1		1.6	1.4
	Median	4.8		5.6	5.1
	Minimum	4		4	3
	Maximum	7		7	9
Change from Day 0	N	6	0	5	14
	Mean	0.1		-0.1	-0.2
	SD	0.8		1.0	1.1
	Median	0.15		0.30	0.00
	Minimum	-1		-2	-3
	Maximum	1		1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	5.1		5.9	6.2
	SD	0.9		2.1	0.9
	Median	4.8		5.1	5.8
	Minimum	4		4	6
	Maximum	6		9	8
Change from Day 0	N	6	0	5	4
	Mean	0.1		0.5	0.0
	SD	0.7		1.2	0.6
	Median	0.15		0.30	0.15
	Minimum	-1		-1	-1
	Maximum	1		2	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.2.15 - Laboratory Test Results - Hematology: Leukocytes

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		5.2	5.0	
	SD		1.3	.	
	Median		4.9	5.0	
	Minimum		4	5	
	Maximum		7	5	
Change from Day 0	N	0	3	1	0
	Mean		1.3	-0.3	
	SD		0.5	.	
	Median		1.30	-0.30	
	Minimum		1	-0	
	Maximum		2	-0	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Negative	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.1 - Laboratory Test Results - Urinalysis: Bilirubin

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Negative	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Negative	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.2.urin.gluc.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.2.urin.gluc.sas

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Table 14.3.4.3.2 - Laboratory Test Results - Urinalysis: Glucose

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Negative	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.2.urin.gluc.sas



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Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Negative	6 (100.0%)	5 ( 83.3%)	4 ( 66.7%)	5 ( 83.3%)	6 (100.0%)
	Trace	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 ( 83.3%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.3.urin.ket.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	15 ( 93.8%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.3.urin.ket.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	9 ( 90.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 10.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Negative	6 (100.0%)	1 ( 33.3%)	5 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	2 ( 66.7%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	13 ( 92.9%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 7.1%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.3.urin.ket.sas

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Protocol: LB-102-001

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Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.3.urin.ket.sas

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Protocol: LB-102-001

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Table 14.3.4.3.3 - Laboratory Test Results - Urinalysis: Ketones

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Negative	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.3.urin.ket.sas



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Protocol: LB-102-001

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Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Negative	5 ( 83.3%)	5 ( 83.3%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.4.urin.leu.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Negative	5 ( 83.3%)	5 ( 83.3%)	6 (100.0%)	15 ( 93.8%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
	2+	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	15 ( 93.8%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Protocol: LB-102-001

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Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Negative	6 (100.0%)	3 (100.0%)	5 (100.0%)	5 ( 83.3%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	4 ( 66.7%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.4.urin.leu.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	12 ( 85.7%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 14.3%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Negative	5 ( 83.3%)	0 ( 0.0%)	5 (100.0%)	3 ( 75.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 25.0%)
	1+	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Protocol: LB-102-001

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Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.4 - Laboratory Test Results - Urinalysis: Leukocyte Esterase

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Negative	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.5 - Laboratory Test Results - Urinalysis: Nitrite

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Day 0	N	6	6	6	6	6
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Day 2	N	6	6	6	6	6
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Day 4	N	0	0	0	0	0
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.5.urin.nit.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.4.3.5 - Laboratory Test Results - Urinalysis: Nitrite

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Day 0	N	6	6	6	16
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Day 2	N	0	0	0	10
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
Day 4	N	6	3	5	6
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.5 - Laboratory Test Results - Urinalysis: Nitrite

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Day 15	N	0	0	0	0	0
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Early Termination	N	0	0	0	0	0
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.5 - Laboratory Test Results - Urinalysis: Nitrite

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
Day 15	N	6	0	5	4
	Positive	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
Early Termination	N	0	3	1	0
	Positive	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)
	Negative	0 ( 0.0%)	2 ( 66.7%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.4.3.6.urin.occ.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	15 ( 93.8%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Negative	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Negative	6 (100.0%)	5 ( 83.3%)	6 (100.0%)	5 ( 83.3%)	5 ( 83.3%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
	1+	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.6 - Laboratory Test Results - Urinalysis: Occult Blood

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Negative	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	6.2	6.6	6.3	6.3	6.8
	SD	0.6	0.4	0.9	0.7	0.5
	Median	6.3	6.5	6.0	6.3	6.8
	Minimum	6	6	6	6	6
	Maximum	7	7	8	7	8
Day 0	N	6	6	5	6	6
	Mean	6.3	6.7	6.2	6.7	6.8
	SD	0.8	0.8	0.8	0.4	0.8
	Median	6.3	7.0	6.0	6.8	7.0
	Minimum	5	6	6	6	6
	Maximum	7	8	8	7	8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	5.9	6.1	6.7	6.4
	SD	0.7	0.5	0.8	0.5
	Median	6.3	6.0	6.5	6.5
	Minimum	5	6	6	6
	Maximum	7	7	8	7
Day 0	N	6	6	6	16
	Mean	5.8	5.8	6.6	6.4
	SD	0.4	0.5	1.0	0.6
	Median	5.8	5.8	6.8	6.5
	Minimum	6	5	6	6
	Maximum	7	7	8	8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	5.8	6.1	5.8	5.7	6.3
	SD	0.4	0.5	0.4	0.4	0.3
	Median	5.8	6.0	5.8	5.8	6.5
	Minimum	6	6	6	5	6
	Maximum	7	7	7	6	7
Change from Day 0	N	6	6	5	6	6
	Mean	-0.4	-0.6	-0.4	-1.0	-0.4
	SD	0.7	1.2	0.7	0.5	1.0
	Median	-0.8	-1.0	-0.5	-1.0	-0.5
	Minimum	-1	-2	-2	-2	-2
	Maximum	1	2	1	-1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				5.8
	SD				0.3
	Median				6.0
	Minimum				6
	Maximum				6
Change from Day 0	N	0	0	0	10
	Mean				-0.8
	SD				0.5
	Median				-0.5
	Minimum				-2
	Maximum				0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	5.6	5.7	6.1	5.6
	SD	0.2	0.3	1.1	0.2
	Median	5.5	5.5	5.5	5.5
	Minimum	6	6	6	6
	Maximum	6	6	8	6
Change from Day 0	N	6	3	5	6
	Mean	-0.3	-0.2	-0.4	-0.6
	SD	0.4	0.6	0.5	0.5
	Median	0.0	-0.5	0.0	-0.8
	Minimum	-1	-1	-1	-1
	Maximum	0	1	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	6.4	6.7	6.6	6.2	6.6
	SD	0.9	0.8	1.1	0.6	0.4
	Median	6.0	7.0	6.3	6.3	6.5
	Minimum	6	6	6	6	6
	Maximum	8	8	9	7	7
Change from Day 0	N	6	6	5	6	6
	Mean	0.2	0.0	0.0	-0.5	-0.2
	SD	0.8	0.8	1.2	0.3	0.6
	Median	0.0	0.0	0.0	-0.5	-0.5
	Minimum	-1	-1	-2	-1	-1
	Maximum	1	2	1	0	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	5.5		6.4	6.3
	SD	0.0		0.7	0.8
	Median	5.5		6.5	6.0
	Minimum	6		6	6
	Maximum	6		8	8
Change from Day 0	N	6	0	5	14
	Mean	-0.3		-0.1	-0.1
	SD	0.4		0.7	0.6
	Median	-0.3		-0.5	0.0
	Minimum	-1		-1	-1
	Maximum	0		1	1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	5.7		6.6	6.0
	SD	0.3		1.0	1.1
	Median	5.5		6.5	5.8
	Minimum	6		6	5
	Maximum	6		8	8
Change from Day 0	N	6	0	5	4
	Mean	-0.2		0.1	-0.1
	SD	0.3		1.6	1.5
	Median	0.0		0.0	-0.5
	Minimum	-1		-2	-2
	Maximum	0		3	2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.7 - Laboratory Test Results - Urinalysis: pH

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		5.5	6.5	
	SD		0.5	.	
	Median		5.5	6.5	
	Minimum		5	7	
	Maximum		6	7	
Change from Day 0	N	0	3	1	0
	Mean		-0.2	-0.5	
	SD		0.3	.	
	Median		0.0	-0.5	
	Minimum		-1	-1	
	Maximum		0	-1	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Negative	6 (100.0%)	5 ( 83.3%)	5 ( 83.3%)	5 ( 83.3%)	6 (100.0%)
	Trace	0 ( 0.0%)	1 ( 16.7%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 ( 83.3%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	15 ( 93.8%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Negative	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Negative	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	13 ( 92.9%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 7.1%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Negative	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Negative	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.8 - Laboratory Test Results - Urinalysis: Protein

Visits	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Negative	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Trace	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	1+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	2+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	3+	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	4	4	5	5
	Mean	1.0	1.0	1.0	1.0	1.0
	SD	0.0	0.0	0.0	0.0	0.0
	Median	1.0	1.0	1.0	1.0	1.0
	Minimum	1.0	1.0	1.0	1.0	1.0
	Maximum	1.0	1.0	1.0	1.0	1.0
Day 0	N	5	5	6	4	2
	Mean	1.0	1.0	1.0	1.0	1.0
	SD	0.0	0.0	0.0	0.0	0.0
	Median	1.0	1.0	1.0	1.0	1.0
	Minimum	1.0	1.0	1.0	1.0	1.0
	Maximum	1.0	1.0	1.0	1.0	1.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	5	6	6	12
	Mean	1.0	1.0	1.0	1.0
	SD	0.0	0.0	0.0	0.0
	Median	1.0	1.0	1.0	1.0
	Minimum	1.0	1.0	1.0	1.0
	Maximum	1.0	1.0	1.0	1.0
Day 0	N	6	5	5	15
	Mean	1.0	1.0	1.0	1.0
	SD	0.0	0.0	0.0	0.0
	Median	1.0	1.0	1.0	1.0
	Minimum	1.0	1.0	1.0	1.0
	Maximum	1.0	1.0	1.0	1.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	4	6	6	6	6
	Mean	1.0	1.0	1.0	1.0	1.0
	SD	0.0	0.0	0.0	0.0	0.0
	Median	1.0	1.0	1.0	1.0	1.0
	Minimum	1.0	1.0	1.0	1.0	1.0
	Maximum	1.0	1.0	1.0	1.0	1.0
Change from Day 0	N	3	5	6	4	2
	Mean	0.014	0.004	0.007	0.006	0.006
	SD	0.0	0.0	0.0	0.0	0.0
	Median	0.017	0.005	0.005	0.007	0.006
	Minimum	0.007	-.009	-.001	-.005	-.004
	Maximum	0.0	0.0	0.0	0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				1.0
	SD				0.0
	Median				1.0
	Minimum				1.0
	Maximum				1.0
Change from Day 0	N	0	0	0	9
	Mean				0.007
	SD				0.0
	Median				0.005
	Minimum				-.001
	Maximum				0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	1.0	1.0	1.0	1.0
	SD	0.0	0.0	0.0	0.0
	Median	1.0	1.0	1.0	1.0
	Minimum	1.0	1.0	1.0	1.0
	Maximum	1.0	1.0	1.0	1.0
Change from Day 0	N	6	2	5	6
	Mean	-.004	0.007	0.005	-.001
	SD	0.0	0.0	0.0	0.0
	Median	-.005	0.007	0.006	-.002
	Minimum	-.009	-.002	-.004	-.010
	Maximum	0.0	0.0	0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	4	5	5	5
	Mean	1.0	1.0	1.0	1.0	1.0
	SD	0.0	0.0	0.0	0.0	0.0
	Median	1.0	1.0	1.0	1.0	1.0
	Minimum	1.0	1.0	1.0	1.0	1.0
	Maximum	1.0	1.0	1.0	1.0	1.0
Change from Day 0	N	5	3	5	4	2
	Mean	0.002	0.004	0.010	0.006	0.001
	SD	0.0	0.0	0.0	0.0	0.0
	Median	0.004	0.008	0.008	0.004	0.001
	Minimum	-.004	-.007	0.000	-.004	0.000
	Maximum	0.0	0.0	0.0	0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	13
	Mean	1.0		1.0	1.0
	SD	0.0		0.0	0.0
	Median	1.0		1.0	1.0
	Minimum	1.0		1.0	1.0
	Maximum	1.0		1.0	1.0
Change from Day 0	N	6	0	5	12
	Mean	-.002		0.006	-.003
	SD	0.0		0.0	0.0
	Median	-.002		0.006	-.002
	Minimum	-.003		-.003	-.013
	Maximum	0.0		0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	4	0	5	4
	Mean	1.0		1.0	1.0
	SD	0.0		0.0	0.0
	Median	1.0		1.0	1.0
	Minimum	1.0		1.0	1.0
	Maximum	1.0		1.0	1.0
Change from Day 0	N	4	0	5	4
	Mean	0.002		0.003	0.001
	SD	0.0		0.0	0.0
	Median	0.000		0.006	0.001
	Minimum	0.000		-.016	-.001
	Maximum	0.0		0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.4.3.9 - Laboratory Test Results - Urinalysis: Specific Gravity

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		1.0	1.0	
	SD		0.0	.	
	Median		1.0	1.0	
	Minimum		1.0	1.0	
	Maximum		1.0	1.0	
Change from Day 0	N	0	3	0	0
	Mean		0.000		
	SD		0.0		
	Median		0.001		
	Minimum		-.003		
	Maximum		0.0		

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	0.2	0.3	0.3	0.2	0.2
	SD	0.0	0.3	0.3	0.0	0.0
	Median	0.2	0.2	0.2	0.2	0.2
	Minimum	0.2	0.2	0.2	0.2	0.2
	Maximum	0.2	1.0	1.0	0.2	0.2
Day 0	N	6	6	6	6	6
	Mean	0.2	0.5	0.2	0.3	0.3
	SD	0.0	0.4	0.0	0.3	0.3
	Median	0.2	0.2	0.2	0.2	0.2
	Minimum	0.2	0.2	0.2	0.2	0.2
	Maximum	0.2	1.0	0.2	1.0	1.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	0.5	0.2	0.2	0.3
	SD	0.4	0.0	0.0	0.3
	Median	0.2	0.2	0.2	0.2
	Minimum	0.2	0.2	0.2	0.2
	Maximum	1.0	0.2	0.2	1.0
Day 0	N	6	6	6	16
	Mean	0.5	0.3	0.3	0.4
	SD	0.4	0.3	0.3	0.3
	Median	0.2	0.2	0.2	0.2
	Minimum	0.2	0.2	0.2	0.2
	Maximum	1.0	1.0	1.0	1.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Mean	0.2	0.2	0.2	0.2	0.2
	SD	0.0	0.0	0.0	0.0	0.0
	Median	0.2	0.2	0.2	0.2	0.2
	Minimum	0.2	0.2	0.2	0.2	0.2
	Maximum	0.2	0.2	0.2	0.2	0.2
Change from Day 0	N	6	6	6	6	6
	Mean	0.0	-0.3	0.0	-0.1	-0.1
	SD	0.0	0.4	0.0	0.3	0.3
	Median	0.0	0.0	0.0	0.0	0.0
	Minimum	0.0	-0.8	0.0	-0.8	-0.8
	Maximum	0.0	0.0	0.0	0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	0	0	0	10
	Mean				0.2
	SD				0.0
	Median				0.2
	Minimum				0.2
	Maximum				0.2
Change from Day 0	N	0	0	0	10
	Mean				0.0
	SD				0.0
	Median				0.0
	Minimum				0.0
	Maximum				0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 4	N	6	3	5	6
	Mean	0.2	0.2	0.2	0.2
	SD	0.0	0.0	0.0	0.0
	Median	0.2	0.2	0.2	0.2
	Minimum	0.2	0.2	0.2	0.2
	Maximum	0.2	0.2	0.2	0.2
Change from Day 0	N	6	3	5	6
	Mean	-0.3	0.0	-0.2	-0.4
	SD	0.4	0.0	0.4	0.4
	Median	0.0	0.0	0.0	-0.4
	Minimum	-0.8	0.0	-0.8	-0.8
	Maximum	0.0	0.0	0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Mean	0.2	0.5	0.3	0.3	0.2
	SD	0.0	0.4	0.3	0.3	0.0
	Median	0.2	0.2	0.2	0.2	0.2
	Minimum	0.2	0.2	0.2	0.2	0.2
	Maximum	0.2	1.0	1.0	1.0	0.2
Change from Day 0	N	6	6	6	6	6
	Mean	0.0	0.0	0.1	0.0	-0.1
	SD	0.0	0.0	0.3	0.5	0.3
	Median	0.0	0.0	0.0	0.0	0.0
	Minimum	0.0	0.0	0.0	-0.8	-0.8
	Maximum	0.0	0.0	0.8	0.8	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Mean	0.2		0.2	0.2
	SD	0.0		0.0	0.0
	Median	0.2		0.2	0.2
	Minimum	0.2		0.2	0.2
	Maximum	0.2		0.2	0.2
Change from Day 0	N	6	0	5	14
	Mean	-0.3		-0.2	-0.1
	SD	0.4		0.4	0.3
	Median	0.0		0.0	0.0
	Minimum	-0.8		-0.8	-0.8
	Maximum	0.0		0.0	0.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 15	N	6	0	5	4
	Mean	0.6		0.2	0.6
	SD	0.4		0.0	0.5
	Median	0.6		0.2	0.6
	Minimum	0.2		0.2	0.2
	Maximum	1.0		0.2	1.0
Change from Day 0	N	6	0	5	4
	Mean	0.1		-0.2	0.0
	SD	0.3		0.4	0.7
	Median	0.0		0.0	0.0
	Minimum	0.0		-0.8	-0.8
	Maximum	0.8		0.0	0.8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Change from Day 0	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.4.3.10 - Laboratory Test Results - Urinalysis: Urobilinogen

Visits	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Early Termination	N	0	3	1	0
	Mean		0.2	0.2	
	SD		0.0	.	
	Median		0.2	0.2	
	Minimum		0.2	0.2	
	Maximum		0.2	0.2	
Change from Day 0	N	0	3	1	0
	Mean		-0.3	0.0	
	SD		0.5	.	
	Median		0.0	0.0	
	Minimum		-0.8	0.0	
	Maximum		0.0	0.0	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	120.5	116.5	119.2	114.2	118.8
	SD	15.3	13.2	6.4	6.9	10.1
	Median	118.5	119.5	116.5	112.5	117.0
	Minimum	105	98	114	106	104
	Maximum	139	129	128	125	132
Day 0	N	6	6	6	6	6
	Mean	127.0	117.3	118.3	113.0	121.7
	SD	12.9	10.7	6.3	5.1	17.4
	Median	125.0	121.0	116.5	113.5	120.5
	Minimum	112	99	112	105	94
	Maximum	147	128	129	120	144

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	121.2	110.7	123.5	120.8
	SD	7.8	4.3	6.1	13.6
	Median	118.0	109.5	122.0	119.0
	Minimum	114	107	116	100
	Maximum	132	119	134	148
Day 0	N	6	6	6	16
	Mean	122.0	111.7	113.7	122.1
	SD	8.3	7.4	9.2	12.8
	Median	123.5	110.0	111.5	122.0
	Minimum	109	104	103	104
	Maximum	131	122	127	151

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Day 1	Pre-dose	N	6	6	6	6	6
		Mean	122.2	114.3	115.5	119.0	118.5
		SD	12.0	6.1	6.7	6.7	10.5
		Median	123.5	113.0	114.5	119.5	117.0
		Minimum	107	108	107	111	106
		Maximum	134	122	124	130	133
Day 1	Post 0.5 hr	N	6	6	6	6	6
		Mean	124.2	109.5	113.0	121.0	125.7
		SD	12.3	5.5	8.6	3.9	15.7
		Median	124.0	110.0	113.5	121.5	120.0
		Minimum	111	102	100	115	112
		Maximum	141	117	123	125	156

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)			Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics						
Day 1	Pre-dose	N	6	6	6	16
		Mean	121.8	114.5	119.3	119.9
		SD	10.4	8.5	9.1	12.2
		Median	120.0	113.5	119.5	118.5
		Minimum	108	101	108	102
		Maximum	135	124	129	148
Day 1	Post 0.5 hr	N	6	6	6	16
		Mean	121.7	115.7	120.0	120.7
		SD	7.5	8.5	12.5	11.0
		Median	122.5	116.5	121.5	123.0
		Minimum	112	104	101	94
		Maximum	131	127	136	135

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 0.5 hr	N	6	6	6	6	6
		Mean	2.0	-4.8	-2.5	2.0	7.2
		SD	6.4	6.2	8.7	5.4	13.1
		Median	1.5	-4.0	-2.5	1.5	6.5
		Minimum	-5	-16	-17	-5	-9
		Maximum	11	2	10	11	23
Day 1	Post 1 hr	N	6	6	6	6	6
		Mean	125.0	119.2	116.8	127.2	120.8
		SD	14.4	9.2	9.5	10.0	10.2
		Median	120.0	121.5	120.0	126.5	119.5
		Minimum	111	107	99	115	110
		Maximum	143	129	125	143	138

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 0.5 hr	N	6	6	6	16
		Mean	-0.2	1.2	0.7	0.8
		SD	7.3	8.3	6.3	7.5
		Median	0.0	4.0	-1.0	1.5
		Minimum	-9	-11	-7	-13
		Maximum	10	10	9	12
Day 1	Post 1 hr	N	6	6	6	16
		Mean	120.0	119.5	120.5	116.7
		SD	7.3	11.0	10.8	11.6
		Median	121.0	123.0	122.5	113.0
		Minimum	111	104	103	98
		Maximum	131	131	131	138

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 1 hr	N	6	6	6	6	6
		Mean	2.8	4.8	1.3	8.2	2.3
		SD	8.6	6.6	11.2	12.1	12.4
		Median	5.5	4.5	3.0	10.0	0.5
		Minimum	-9	-2	-18	-7	-15
		Maximum	13	12	14	22	17
Day 1	Post 1.5 hrs	N	6	6	6	6	6
		Mean	126.8	113.5	112.5	120.7	121.8
		SD	16.9	5.2	11.9	7.5	6.1
		Median	118.0	114.5	115.0	119.5	123.0
		Minimum	113	105	91	110	111
		Maximum	149	120	126	131	129

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1 hr	N	6	6	6	16
		Mean	-1.8	5.0	1.2	-3.3
		SD	6.5	8.2	4.0	10.0
		Median	-3.0	5.0	0.5	-3.0
		Minimum	-10	-7	-5	-34
		Maximum	8	16	6	7
Day 1	Post 1.5 hrs	N	6	6	6	16
		Mean	118.7	118.7	123.0	115.3
		SD	6.2	13.3	15.3	10.6
		Median	119.5	115.5	123.5	114.0
		Minimum	108	104	105	93
		Maximum	127	136	144	134

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas



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Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	6	6
		Mean	4.7	-0.8	-3.0	1.7	3.3
		SD	12.1	3.3	12.4	7.7	9.3
		Median	6.5	-0.5	2.0	2.5	0.5
		Minimum	-14	-5	-26	-10	-6
		Maximum	18	3	8	12	15
Day 1	Post 2 hrs	N	6	6	6	6	6
		Mean	126.0	120.3	113.2	123.0	121.8
		SD	17.7	7.8	13.6	8.0	9.9
		Median	120.5	119.0	114.0	121.0	122.5
		Minimum	108	112	92	113	104
		Maximum	153	130	132	134	133

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	16
		Mean	-3.2	4.2	3.7	-4.6
		SD	5.6	12.4	7.9	11.0
		Median	-1.0	5.0	5.0	-3.5
		Minimum	-12	-15	-9	-38
		Maximum	2	21	15	9
Day 1	Post 2 hrs	N	6	6	6	16
		Mean	123.5	118.3	121.0	119.6
		SD	4.7	10.5	10.5	12.5
		Median	123.0	120.0	124.0	120.0
		Minimum	116	103	105	95
		Maximum	129	129	133	138

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Change from pre-dose	Post 2 hrs	N	6	6	6	6	6
		Mean	3.8	6.0	-2.3	4.0	3.3
		SD	13.1	8.5	13.0	10.8	13.9
		Median	6.5	8.0	0.0	1.0	-2.0
		Minimum	-13	-9	-25	-9	-10
		Maximum	23	14	10	21	23
Day 1	Post 4 hrs	N	6	6	6	6	6
		Mean	121.5	114.0	111.7	118.7	126.2
		SD	10.1	5.9	6.7	9.0	12.4
		Median	122.0	114.5	114.0	117.0	127.0
		Minimum	109	107	98	107	105
		Maximum	138	121	116	132	142

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	16
		Mean	1.7	3.8	1.7	-0.3
		SD	6.1	7.1	9.5	12.3
		Median	3.0	3.0	-2.0	2.0
		Minimum	-7	-5	-3	-39
		Maximum	8	16	21	16
Day 1	Post 4 hrs	N	6	6	6	16
		Mean	121.5	116.8	117.2	115.2
		SD	8.6	6.7	14.1	14.9
		Median	120.5	116.5	118.5	117.0
		Minimum	112	106	99	85
		Maximum	137	126	137	134

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 4 hrs	N	6	6	6	6	6
		Mean	-0.7	-0.3	-3.8	-0.3	7.7
		SD	9.2	8.4	9.6	11.9	13.1
		Median	-1.0	-0.5	-3.0	-3.0	9.5
		Minimum	-12	-13	-19	-13	-9
		Maximum	11	13	7	21	27
Day 1	Post 5 hrs	N	6	6	6	6	6
		Mean	126.2	119.3	117.2	117.7	116.5
		SD	11.5	14.1	5.5	9.2	13.3
		Median	122.5	120.5	117.5	115.0	115.0
		Minimum	113	103	108	110	101
		Maximum	143	134	125	133	137

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 4 hrs	N	6	6	6	16
		Mean	-0.3	2.3	-2.2	-4.8
		SD	8.3	7.3	6.8	13.6
		Median	1.5	2.5	-2.5	-3.0
		Minimum	-11	-8	-9	-33
		Maximum	11	14	9	14
Day 1	Post 5 hrs	N	6	6	6	16
		Mean	122.3	113.0	119.0	118.9
		SD	5.5	11.3	9.8	12.7
		Median	121.5	113.0	120.0	119.0
		Minimum	116	96	108	95
		Maximum	132	128	132	137

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Change from pre-dose	Post 5 hrs	N	6	6	6	6	6
		Mean	4.0	5.0	1.7	-1.3	-2.0
		SD	8.9	15.0	7.3	8.5	15.1
		Median	8.0	6.5	4.0	-2.0	-0.5
		Minimum	-10	-18	-9	-11	-23
		Maximum	12	23	11	14	20
Day 1	Post 8 hrs	N	6	6	6	6	6
		Mean	120.7	110.2	118.2	109.8	118.3
		SD	11.7	7.9	7.1	5.1	8.8
		Median	119.0	108.0	117.5	109.0	117.5
		Minimum	106	102	110	104	109
		Maximum	139	123	129	119	133

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 5 hrs	N	6	6	6	16
		Mean	0.5	-1.5	-0.3	-1.1
		SD	12.4	6.0	4.2	7.8
		Median	3.5	-4.5	-1.0	-0.5
		Minimum	-17	-7	-6	-18
		Maximum	13	8	5	11
Day 1	Post 8 hrs	N	6	6	6	16
		Mean	117.2	110.7	107.3	116.0
		SD	9.1	7.1	6.9	13.5
		Median	116.5	107.5	106.0	117.5
		Minimum	107	105	101	92
		Maximum	128	124	116	135

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Change from pre-dose	Post 8 hrs	N	6	6	6	6	6
		Mean	-1.5	-4.2	2.7	-9.2	-0.2
		SD	7.1	7.3	10.5	8.2	11.8
		Median	-1.0	-6.5	4.5	-6.5	-2.5
		Minimum	-12	-13	-12	-21	-17
		Maximum	9	8	18	0	16
Day 1	Post 12 hrs	N	6	6	6	5	6
		Mean	122.7	119.2	112.0	112.8	116.3
		SD	12.4	7.6	6.1	6.2	16.3
		Median	120.5	118.0	112.5	112.0	118.0
		Minimum	109	112	105	106	94
		Maximum	138	132	120	121	143

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 8 hrs	N	6	6	6	16
		Mean	-4.7	-3.8	-12.0	-3.9
		SD	3.8	5.8	8.7	10.0
		Median	-6.0	-6.0	-13.0	-0.5
		Minimum	-8	-10	-23	-29
		Maximum	0	6	2	10
Day 1	Post 12 hrs	N	6	6	6	16
		Mean	113.8	116.3	108.3	116.6
		SD	5.5	10.0	11.2	11.0
		Median	116.0	120.0	112.0	115.0
		Minimum	106	98	93	103
		Maximum	119	125	119	138

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 12 hrs	N	6	6	6	5	6
		Mean	0.5	4.8	-3.5	-6.2	-2.2
		SD	7.0	7.6	5.3	7.0	15.1
		Median	4.5	6.5	-3.5	-3.0	0.5
		Minimum	-9	-9	-11	-18	-26
		Maximum	6	12	5	0	12
Day 2	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 12 hrs	N	6	6	6	16
		Mean	-8.0	1.8	-11.0	-3.3
		SD	8.2	7.9	9.4	6.6
		Median	-7.5	-3.0	-12.0	-1.5
		Minimum	-17	-4	-21	-14
		Maximum	0	13	6	8
Day 2	Pre-dose	N	6	6	6	6
		Mean	113.2	112.8	111.2	121.8
		SD	6.8	8.8	12.4	8.7
		Median	112.5	116.0	110.0	123.0
		Minimum	105	98	95	110
		Maximum	121	121	132	134

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	6	6	6
		Mean	-8.7	-1.7	-8.2	1.2
		SD	12.8	8.6	6.7	5.5
		Median	-6.5	-0.5	-11.0	2.0
		Minimum	-26	-17	-14	-8
		Maximum	6	6	3	8
Day 2	Post 2 hrs	N	6	6	6	6
		Mean	115.5	113.7	109.8	120.7
		SD	6.2	6.3	8.8	15.3
		Median	115.5	113.0	110.0	125.5
		Minimum	108	105	95	99
		Maximum	125	124	122	140

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 24 hrs	N	6	6	6	6	6
		Mean	119.5	114.3	112.8	120.5	117.5
		SD	13.6	11.4	5.3	13.1	19.8
		Median	116.0	114.5	113.5	115.0	115.0
		Minimum	108	101	106	109	91
		Maximum	143	128	121	139	147

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	6
		Mean	-6.3	-0.8	-9.5	0.0
		SD	7.2	6.6	7.4	4.7
		Median	-4.5	-1.0	-10.0	-1.0
		Minimum	-19	-7	-19	-4
		Maximum	0	11	2	9
Day 2	Post 24 hrs	N	0	0	0	10
		Mean				115.0
		SD				8.5
		Median				119.0
		Minimum				98
		Maximum				124

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas



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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 24 hrs	N	6	6	6	6	6
		Mean	-2.7	0.0	-2.7	1.5	-1.0
		SD	9.3	13.2	8.6	17.2	22.6
		Median	-5.5	1.5	-3.5	-0.5	-6.0
		Minimum	-12	-20	-11	-20	-23
		Maximum	13	20	10	26	41
Day 3	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 24 hrs	N	0	0	0	10
		Mean				-4.5
		SD				11.4
		Median				-4.0
		Minimum				-24
		Maximum				15
Day 3	Pre-dose	N	6	5	6	6
		Mean	111.7	111.4	112.2	119.2
		SD	6.0	7.0	6.9	8.4
		Median	112.0	112.0	111.5	120.0
		Minimum	105	100	103	104
		Maximum	118	118	123	129

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	5	6	6
		Mean	-10.2	-5.8	-7.2	-1.5
		SD	9.3	5.8	3.8	6.3
		Median	-14.5	-6.0	-5.5	-2.0
		Minimum	-19	-12	-12	-11
		Maximum	3	1	-4	8
Day 3	Post 2 hrs	N	6	4	6	6
		Mean	117.0	114.5	113.0	119.7
		SD	3.1	7.3	14.4	11.4
		Median	117.0	117.0	110.0	117.5
		Minimum	113	104	93	109
		Maximum	122	120	133	137

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 48 hrs	N	6	6	6	6	6
		Mean	123.2	120.2	114.7	116.8	123.8
		SD	12.2	17.2	7.9	7.7	10.3
		Median	123.5	119.0	116.5	114.5	119.5
		Minimum	108	97	101	107	113
		Maximum	138	147	122	127	139

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	4	6	6
		Mean	-4.8	-4.0	-6.3	-1.0
		SD	9.3	3.3	7.3	10.4
		Median	-2.5	-4.0	-6.0	-2.0
		Minimum	-17	-8	-15	-15
		Maximum	7	0	5	14
Day 3	Post 48 hrs	N	0	0	0	10
		Mean				117.8
		SD				11.4
		Median				116.5
		Minimum				103
		Maximum				139

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 48 hrs	N	6	6	6	6	6
		Mean	1.0	5.8	-0.8	-2.2	5.3
		SD	7.9	18.5	7.3	9.1	14.4
		Median	2.5	1.5	-2.0	1.0	0.0
		Minimum	-10	-12	-10	-14	-7
		Maximum	12	39	10	6	33
Day 4	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 48 hrs	N	0	0	0	10
		Mean				-1.7
		SD				13.0
		Median				-3.0
		Minimum				-16
		Maximum				25
Day 4	Pre-dose	N	6	3	5	6
		Mean	115.0	104.7	111.8	120.0
		SD	7.7	7.6	15.5	6.4
		Median	112.5	108.0	110.0	121.0
		Minimum	108	96	92	112
		Maximum	126	110	131	127

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 4	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	3	5	6
		Mean	-6.8	-12.0	-6.4	-0.7
		SD	11.1	4.6	6.7	7.9
		Median	-5.5	-13.0	-5.0	-0.5
		Minimum	-25	-16	-16	-11
		Maximum	7	-7	2	10
Day 4	Post 2 hrs	N	6	3	5	6
		Mean	114.5	113.7	113.2	118.2
		SD	6.9	16.1	11.0	13.8
		Median	118.0	107.0	110.0	114.5
		Minimum	103	102	103	105
		Maximum	120	132	132	137

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	3	5	6
		Mean	-7.3	-3.0	-5.0	-2.5
		SD	8.3	19.1	7.0	11.2
		Median	-7.0	-5.0	-5.0	-0.5
		Minimum	-17	-21	-16	-21
		Maximum	1	17	3	9
Day 5	Pre-dose	N	6	0	5	4
		Mean	115.7		112.0	122.5
		SD	14.4		9.3	14.5
		Median	111.0		112.0	124.5
		Minimum	104		101	103
		Maximum	143		126	138

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-6.2		-6.2	-2.3
		SD	9.3		6.8	6.3
		Median	-6.5		-3.0	-4.5
		Minimum	-20		-14	-7
		Maximum	8		0	7
Day 5	Post 2 hrs	N	6	0	5	4
		Mean	119.2		116.2	130.3
		SD	6.1		13.3	22.2
		Median	120.5		117.0	131.5
		Minimum	111		95	106
		Maximum	127		131	152

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-2.7		-2.0	5.5
		SD	11.7		7.7	15.4
		Median	-5.0		2.0	6.0
		Minimum	-14		-13	-11
		Maximum	19		5	21
Day 6	Pre-dose	N	6	0	5	4
		Mean	112.7		112.2	122.8
		SD	7.7		6.8	8.4
		Median	109.0		109.0	121.0
		Minimum	106		108	115
		Maximum	123		124	134

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-9.2		-6.0	-2.0
		SD	9.2		6.0	7.7
		Median	-8.5		-5.0	-0.5
		Minimum	-25		-16	-12
		Maximum	1		0	5
Day 6	Post 2 hrs	N	6	0	5	4
		Mean	114.2		114.0	120.5
		SD	7.6		14.6	16.0
		Median	114.5		116.0	115.0
		Minimum	102		91	108
		Maximum	125		131	144

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-7.7		-4.2	-4.3
		SD	9.4		9.7	12.8
		Median	-8.0		1.0	-8.0
		Minimum	-21		-17	-14
		Maximum	7		5	13
Day 7	Pre-dose	N	6	0	5	4
		Mean	117.8		109.8	119.8
		SD	5.9		13.2	8.7
		Median	117.0		105.0	123.0
		Minimum	108		94	107
		Maximum	124		124	126

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-4.0		-8.4	-5.0
		SD	9.1		3.7	2.2
		Median	-3.0		-9.0	-4.5
		Minimum	-18		-14	-8
		Maximum	9		-5	-3
Day 7	Post 2 hrs	N	6	0	5	4
		Mean	109.2		113.6	119.5
		SD	4.4		12.1	12.6
		Median	110.0		118.0	121.0
		Minimum	101		100	105
		Maximum	114		128	131

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 8		N	6	6	6	6	6
		Mean	126.8	117.8	123.8	116.7	120.8
		SD	14.7	9.3	13.5	2.1	14.1
		Median	124.0	117.5	121.0	117.0	122.5
		Minimum	110	104	108	113	102
		Maximum	149	133	148	119	141

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-12.7		-4.6	-5.3
		SD	10.1		7.1	6.9
		Median	-11.0		-8.0	-3.5
		Minimum	-26		-12	-15
		Maximum	1		6	1
Day 8		N	6	0	5	14
		Mean	115.5		108.4	119.6
		SD	10.7		8.9	12.5
		Median	114.5		108.0	118.5
		Minimum	105		100	104
		Maximum	135		122	149

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	6	6	6	6	6
	Mean	4.7	3.5	8.3	-2.3	2.3
	SD	9.1	7.2	16.4	5.0	14.8
	Median	1.5	3.0	11.5	-2.0	1.5
	Minimum	-5	-5	-16	-11	-18
	Maximum	19	12	31	3	23
Day 9	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	14
	Mean	-6.3		-9.8	-1.4
	SD	6.7		5.4	8.1
	Median	-5.5		-7.0	-2.5
	Minimum	-18		-17	-16
	Maximum	2		-4	14
Day 9	N	6	0	5	4
	Mean	114.3		112.0	126.5
	SD	9.3		5.0	9.7
	Median	114.5		113.0	127.5
	Minimum	102		104	114
	Maximum	130		117	137

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	-7.5		-6.2	1.8
	SD	11.9		8.6	4.0
	Median	-5.0		-10.0	2.0
	Minimum	-31		-15	-3
	Maximum	1		3	6
Day 15	N	6	0	5	4
	Mean	115.8		118.6	120.5
	SD	11.6		13.7	10.4
	Median	116.5		114.0	124.0
	Minimum	98		101	106
	Maximum	134		133	128

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	-6.0		0.4	-4.3
	SD	8.3		7.6	4.2
	Median	-3.0		3.0	-3.5
	Minimum	-21		-13	-10
	Maximum	2		5	0
Early Termination	N	0	3	1	0
	Mean		118.7	122.0	
	SD		10.4	.	
	Median		122.0	122.0	
	Minimum		107	122	
	Maximum		127	122	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Systolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	0	3	1	0
	Mean		6.3	-3.0	
	SD		3.5	.	
	Median		6.0	-3.0	
	Minimum		3	-3	
	Maximum		10	-3	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	80.7	77.2	77.7	74.5	79.0
	SD	6.9	9.4	5.0	3.7	10.2
	Median	80.5	79.5	79.5	74.5	79.5
	Minimum	71	63	68	70	67
	Maximum	88	88	81	79	92
Day 0	N	6	6	6	6	6
	Mean	86.7	76.2	79.5	75.5	77.0
	SD	6.4	8.5	5.9	4.6	9.3
	Median	87.5	77.5	80.5	76.5	77.5
	Minimum	76	65	72	69	61
	Maximum	95	85	86	81	90

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	81.7	74.2	81.3	77.9
	SD	5.8	3.9	0.8	6.0
	Median	80.5	74.0	81.5	77.0
	Minimum	76	70	80	66
	Maximum	92	79	82	86
Day 0	N	6	6	6	16
	Mean	81.7	73.5	76.3	78.9
	SD	6.0	6.7	5.6	6.7
	Median	82.5	73.5	76.5	78.0
	Minimum	73	66	69	71
	Maximum	91	82	83	92

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Day 1	Pre-dose	N	6	6	6	6	6
		Mean	83.8	73.2	77.2	78.5	75.8
		SD	6.3	4.8	5.3	5.7	10.7
		Median	84.0	75.0	78.5	78.0	76.5
		Minimum	75	65	67	72	61
		Maximum	91	78	82	88	90
Day 1	Post 0.5 hr	N	6	6	6	6	6
		Mean	85.0	71.3	75.8	78.2	81.7
		SD	7.0	6.2	6.1	4.1	13.3
		Median	83.0	74.0	74.5	76.5	77.0
		Minimum	77	63	68	74	67
		Maximum	95	77	84	85	101

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)			Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics						
Day 1	Pre-dose	N	6	6	6	16
		Mean	82.5	76.8	81.0	80.1
		SD	6.3	5.6	6.8	5.8
		Median	82.0	76.0	81.0	79.5
		Minimum	75	71	71	71
		Maximum	93	84	91	91
Day 1	Post 0.5 hr	N	6	6	6	16
		Mean	81.0	76.0	81.2	79.9
		SD	7.1	5.7	8.0	7.5
		Median	79.5	76.0	81.5	79.0
		Minimum	73	67	68	64
		Maximum	90	83	90	95

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 0.5 hr	N	6	6	6	6	6
		Mean	1.2	-1.8	-1.3	-0.3	5.8
		SD	6.1	6.6	7.2	5.6	16.5
		Median	2.5	0.0	0.0	-1.0	4.5
		Minimum	-7	-15	-14	-7	-14
		Maximum	9	3	5	8	34
Day 1	Post 1 hr	N	6	6	6	6	6
		Mean	86.0	72.7	76.8	83.2	80.8
		SD	7.9	7.3	6.5	7.9	10.0
		Median	84.5	74.0	77.5	82.5	76.0
		Minimum	78	59	65	74	72
		Maximum	97	81	84	96	98

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 0.5 hr	N	6	6	6	16
		Mean	-1.5	-0.8	0.2	-0.2
		SD	5.1	2.2	4.1	4.6
		Median	-1.5	0.0	-1.0	0.0
		Minimum	-10	-4	-4	-7
		Maximum	5	2	7	7
Day 1	Post 1 hr	N	6	6	6	16
		Mean	81.5	80.7	80.5	77.9
		SD	7.2	7.8	5.7	7.2
		Median	83.5	81.0	81.0	78.5
		Minimum	72	71	71	65
		Maximum	91	92	87	88

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 1 hr	N	6	6	6	6	6
		Mean	2.2	-0.5	-0.3	4.7	5.0
		SD	4.5	4.2	8.9	7.5	12.6
		Median	2.5	-1.5	0.5	3.0	4.0
		Minimum	-3	-6	-17	-2	-7
		Maximum	7	5	9	17	27
Day 1	Post 1.5 hrs	N	6	6	6	6	6
		Mean	86.0	74.7	74.8	80.2	83.3
		SD	5.5	3.7	8.3	4.5	7.4
		Median	84.0	73.5	76.5	80.0	83.5
		Minimum	81	72	60	74	75
		Maximum	95	82	83	85	92

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1 hr	N	6	6	6	16
		Mean	-1.0	3.8	-0.5	-2.2
		SD	4.5	4.7	2.9	4.7
		Median	-2.5	4.0	0.0	-0.5
		Minimum	-6	-2	-4	-13
		Maximum	7	9	3	4
Day 1	Post 1.5 hrs	N	6	6	6	16
		Mean	80.5	77.7	82.7	76.3
		SD	5.4	7.8	8.1	7.4
		Median	80.0	75.0	84.0	75.5
		Minimum	74	69	73	64
		Maximum	89	90	94	93

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	6	6
		Mean	2.2	1.5	-2.3	1.7	7.5
		SD	4.1	5.0	10.0	3.4	10.7
		Median	3.5	1.5	1.5	2.0	5.5
		Minimum	-5	-4	-22	-3	-3
		Maximum	6	8	5	5	28
Day 1	Post 2 hrs	N	6	6	6	6	6
		Mean	84.3	77.8	76.2	78.8	78.7
		SD	8.8	9.5	9.1	4.6	7.4
		Median	83.0	78.0	77.5	80.5	80.0
		Minimum	74	63	61	70	67
		Maximum	96	90	88	82	88

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	16
		Mean	-2.0	0.8	1.7	-3.8
		SD	5.0	7.0	6.0	4.2
		Median	-2.5	1.5	3.5	-3.0
		Minimum	-9	-10	-7	-10
		Maximum	6	8	9	3
Day 1	Post 2 hrs	N	6	6	6	16
		Mean	83.2	78.8	83.5	79.5
		SD	5.4	6.7	7.8	7.6
		Median	82.0	78.0	86.0	80.0
		Minimum	76	71	72	64
		Maximum	92	87	92	91

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Change from pre-dose	Post 2 hrs	N	6	6	6	6	6
		Mean	0.5	4.7	-1.0	0.3	2.8
		SD	6.2	8.5	10.6	4.9	12.3
		Median	2.0	3.0	1.0	1.0	-2.5
		Minimum	-8	-4	-21	-6	-9
		Maximum	7	16	9	8	22
Day 1	Post 4 hrs	N	6	6	6	6	6
		Mean	83.2	72.2	73.7	77.2	82.3
		SD	5.9	6.4	5.2	6.7	10.2
		Median	82.5	72.5	75.0	75.0	85.0
		Minimum	75	64	67	71	66
		Maximum	93	80	80	90	96

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	16
		Mean	0.7	2.0	2.5	-0.6
		SD	7.3	4.7	7.5	5.0
		Median	-1.0	0.5	2.5	-1.0
		Minimum	-7	-2	-6	-7
		Maximum	14	11	15	8
Day 1	Post 4 hrs	N	6	6	6	16
		Mean	80.3	76.5	76.8	74.3
		SD	4.1	2.6	5.4	9.5
		Median	80.0	76.0	76.5	75.5
		Minimum	76	73	68	51
		Maximum	88	81	83	88

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 4 hrs	N	6	6	6	6	6
		Mean	-0.7	-1.0	-3.5	-1.3	6.5
		SD	5.3	5.0	5.9	8.4	12.4
		Median	-0.5	-0.5	-1.5	-3.0	5.5
		Minimum	-7	-7	-15	-12	-7
		Maximum	7	6	1	13	25
Day 1	Post 5 hrs	N	6	6	6	6	6
		Mean	82.8	74.3	78.0	69.3	76.0
		SD	5.3	5.4	4.2	8.7	12.4
		Median	83.0	75.5	77.5	70.5	72.0
		Minimum	75	68	74	57	61
		Maximum	89	81	86	80	91

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 4 hrs	N	6	6	6	16
		Mean	-2.2	-0.3	-4.2	-5.8
		SD	4.3	4.4	4.1	7.2
		Median	-3.0	0.0	-3.5	-6.5
		Minimum	-7	-7	-10	-26
		Maximum	5	6	0	3
Day 1	Post 5 hrs	N	6	6	6	16
		Mean	79.5	74.8	79.7	76.3
		SD	4.2	5.5	4.5	8.0
		Median	79.5	75.0	81.0	75.5
		Minimum	75	67	72	62
		Maximum	87	81	84	89

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 5 hrs	N	6	6	6	6	6
		Mean	-1.0	1.2	0.8	-9.2	0.2
		SD	2.3	8.4	6.6	6.4	17.0
		Median	-0.5	4.0	-1.0	-9.0	-1.0
		Minimum	-5	-10	-8	-17	-22
		Maximum	1	12	10	-1	30
Day 1	Post 8 hrs	N	6	6	6	6	6
		Mean	83.5	72.3	75.8	72.3	72.5
		SD	6.2	4.3	3.1	2.8	13.0
		Median	82.5	70.0	76.0	72.0	72.5
		Minimum	76	69	71	69	54
		Maximum	92	80	80	76	92

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 5 hrs	N	6	6	6	16
		Mean	-3.0	-2.0	-1.3	-3.8
		SD	4.1	3.7	5.0	4.6
		Median	-3.0	-2.5	-0.5	-3.5
		Minimum	-8	-7	-10	-15
		Maximum	2	4	4	4
Day 1	Post 8 hrs	N	6	6	6	16
		Mean	77.5	74.2	73.2	76.6
		SD	5.5	3.5	4.6	8.2
		Median	77.5	73.0	72.5	78.0
		Minimum	72	71	68	61
		Maximum	87	79	80	90

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Change from pre-dose	Post 8 hrs	N	6	6	6	6	6
		Mean	-0.3	-0.8	-1.3	-6.2	-3.3
		SD	3.9	5.8	2.9	4.0	14.6
		Median	-0.5	-0.5	-1.5	-6.0	-3.0
		Minimum	-6	-8	-4	-12	-19
		Maximum	6	6	4	-1	19
Day 1	Post 12 hrs	N	6	6	6	5	6
		Mean	81.8	76.8	73.7	70.4	76.7
		SD	6.1	7.1	2.9	6.3	13.9
		Median	82.0	77.5	75.0	74.0	73.0
		Minimum	75	65	70	63	63
		Maximum	88	85	76	76	99

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 8 hrs	N	6	6	6	16
		Mean	-5.0	-2.7	-7.8	-3.4
		SD	2.2	2.8	7.0	4.8
		Median	-5.5	-3.0	-10.0	-3.0
		Minimum	-8	-6	-14	-12
		Maximum	-2	1	3	5
Day 1	Post 12 hrs	N	6	6	6	16
		Mean	76.8	75.3	72.3	77.2
		SD	5.6	4.4	7.1	6.2
		Median	76.0	76.0	71.0	76.0
		Minimum	70	67	64	68
		Maximum	85	79	83	87

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 12 hrs	N	6	6	6	5	6
		Mean	-2.0	3.7	-3.5	-7.6	0.8
		SD	2.6	8.3	3.8	6.7	15.5
		Median	-2.5	6.0	-4.0	-8.0	-2.0
		Minimum	-5	-13	-7	-16	-18
		Maximum	2	9	3	0	26
Day 2	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 12 hrs	N	6	6	6	16
		Mean	-5.7	-1.5	-8.7	-2.9
		SD	4.1	4.7	8.2	4.1
		Median	-5.5	-2.5	-8.0	-1.5
		Minimum	-12	-7	-22	-10
		Maximum	0	5	1	2
Day 2	Pre-dose	N	6	6	6	6
		Mean	76.2	75.8	76.7	81.5
		SD	2.5	6.3	7.6	5.5
		Median	76.5	75.0	76.0	80.0
		Minimum	72	67	66	75
		Maximum	79	84	89	88

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	6	6	6
		Mean	-6.3	-1.0	-4.3	1.0
		SD	5.2	4.1	2.0	3.5
		Median	-6.0	0.0	-4.0	1.0
		Minimum	-14	-9	-7	-4
		Maximum	0	3	-2	5
Day 2	Post 2 hrs	N	6	6	6	6
		Mean	76.3	76.3	75.8	77.3
		SD	4.3	4.3	5.9	11.1
		Median	77.0	76.0	77.0	74.0
		Minimum	69	72	65	65
		Maximum	82	82	83	94

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 24 hrs	N	6	6	6	6	6
		Mean	79.3	71.5	74.5	75.0	78.2
		SD	5.1	8.2	6.2	4.3	11.9
		Median	79.5	72.5	75.0	75.5	81.5
		Minimum	72	61	66	69	61
		Maximum	85	82	82	80	93

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	6
		Mean	-6.2	-0.5	-5.2	-3.2
		SD	3.3	2.9	2.8	8.1
		Median	-6.5	-0.5	-5.5	-2.0
		Minimum	-11	-4	-8	-16
		Maximum	-2	3	-1	9
Day 2	Post 24 hrs	N	0	0	0	10
		Mean				74.7
		SD				7.2
		Median				77.5
		Minimum				61
		Maximum				83

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 24 hrs	N	6	6	6	6	6
		Mean	-4.5	-1.7	-2.7	-3.5	2.3
		SD	3.4	8.0	6.2	6.0	14.7
		Median	-5.5	1.5	-1.5	-1.0	0.0
		Minimum	-8	-14	-13	-15	-14
		Maximum	1	6	5	1	22
Day 3	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 24 hrs	N	0	0	0	10
		Mean				-5.1
		SD				6.6
		Median				-6.0
		Minimum				-13
		Maximum				4
Day 3	Pre-dose	N	6	5	6	6
		Mean	78.2	74.4	78.0	80.0
		SD	4.8	6.7	4.4	5.2
		Median	78.0	77.0	80.0	80.0
		Minimum	73	63	71	72
		Maximum	86	79	82	86

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	5	6	6
		Mean	-4.3	-3.6	-3.0	-0.5
		SD	4.2	3.4	3.3	3.4
		Median	-5.5	-4.0	-2.5	0.5
		Minimum	-9	-8	-9	-5
		Maximum	2	1	0	4
Day 3	Post 2 hrs	N	6	4	6	6
		Mean	79.0	76.5	76.5	79.2
		SD	2.3	6.5	7.3	6.9
		Median	78.5	76.5	77.5	78.0
		Minimum	77	69	65	73
		Maximum	83	84	84	87

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 48 hrs	N	6	6	6	6	6
		Mean	81.2	74.7	76.7	76.3	80.8
		SD	4.9	9.6	7.6	5.0	9.1
		Median	80.0	74.5	77.5	77.0	81.5
		Minimum	75	60	64	68	71
		Maximum	88	88	87	81	95

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	4	6	6
		Mean	-3.5	-2.0	-4.5	-1.3
		SD	6.4	5.1	2.1	3.2
		Median	-2.0	-1.0	-5.0	-1.5
		Minimum	-15	-9	-7	-6
		Maximum	4	3	-2	2
Day 3	Post 48 hrs	N	0	0	0	10
		Mean				77.3
		SD				5.2
		Median				78.0
		Minimum				67
		Maximum				84

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 48 hrs	N	6	6	6	6	6
		Mean	-2.7	1.5	-0.5	-2.2	5.0
		SD	2.7	9.0	3.3	3.6	11.9
		Median	-3.5	3.5	-1.0	-1.0	2.0
		Minimum	-6	-10	-4	-7	-10
		Maximum	1	12	5	2	21
Day 4	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 48 hrs	N	0	0	0	10
		Mean				-2.5
		SD				4.6
		Median				-1.0
		Minimum				-11
		Maximum				5
Day 4	Pre-dose	N	6	3	5	6
		Mean	78.5	69.3	76.2	81.3
		SD	4.9	11.6	9.1	8.2
		Median	78.5	75.0	79.0	81.5
		Minimum	72	56	64	73
		Maximum	87	77	87	93

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 4	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	3	5	6
		Mean	-4.0	-7.7	-4.6	0.8
		SD	3.3	7.0	2.5	5.0
		Median	-4.5	-7.0	-4.0	1.0
		Minimum	-8	-15	-7	-6
		Maximum	1	-1	-1	8
Day 4	Post 2 hrs	N	6	3	5	6
		Mean	77.3	74.7	78.4	79.7
		SD	3.6	11.2	6.3	7.8
		Median	77.5	72.0	78.0	76.5
		Minimum	73	65	70	73
		Maximum	83	87	87	90

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	3	5	6
		Mean	-5.2	-2.3	-2.4	-0.8
		SD	5.1	11.9	1.5	6.1
		Median	-3.5	-6.0	-2.0	1.0
		Minimum	-14	-12	-4	-12
		Maximum	-1	11	-1	5
Day 5	Pre-dose	N	6	0	5	4
		Mean	77.0		77.0	81.3
		SD	6.1		5.7	8.7
		Median	75.0		77.0	84.0
		Minimum	71		72	69
		Maximum	85		86	88

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-5.5		-3.8	-0.3
		SD	3.4		4.1	2.9
		Median	-6.0		-5.0	0.5
		Minimum	-9		-8	-4
		Maximum	0		1	2
Day 5	Post 2 hrs	N	6	0	5	4
		Mean	81.5		79.4	85.5
		SD	4.5		9.2	15.5
		Median	82.0		79.0	81.5
		Minimum	75		66	73
		Maximum	87		92	106

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-1.0		-1.4	4.0
		SD	4.4		6.5	9.4
		Median	-1.0		-1.0	2.0
		Minimum	-6		-10	-5
		Maximum	6		7	17
Day 6	Pre-dose	N	6	0	5	4
		Mean	78.5		77.0	84.0
		SD	6.5		4.6	6.3
		Median	76.5		77.0	83.0
		Minimum	72		72	78
		Maximum	88		84	92

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-4.0		-3.8	2.5
		SD	6.8		3.3	4.4
		Median	-2.5		-3.0	3.0
		Minimum	-16		-7	-3
		Maximum	3		1	7
Day 6	Post 2 hrs	N	6	0	5	4
		Mean	76.0		78.2	79.5
		SD	7.2		8.7	6.2
		Median	77.0		82.0	79.0
		Minimum	64		64	73
		Maximum	83		85	87

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-6.5		-2.6	-2.0
		SD	6.4		5.5	5.2
		Median	-6.5		-1.0	-2.0
		Minimum	-14		-9	-7
		Maximum	2		5	3
Day 7	Pre-dose	N	6	0	5	4
		Mean	80.0		75.6	82.5
		SD	7.5		8.9	8.0
		Median	82.0		75.0	85.5
		Minimum	68		65	71
		Maximum	87		86	88

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-2.5		-5.2	1.0
		SD	8.7		3.7	2.9
		Median	0.0		-6.0	1.0
		Minimum	-14		-8	-2
		Maximum	8		1	4
Day 7	Post 2 hrs	N	6	0	5	4
		Mean	74.7		76.2	81.3
		SD	4.5		7.7	6.1
		Median	75.0		79.0	81.0
		Minimum	68		65	76
		Maximum	80		84	87

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 8		N	6	6	6	6	6
		Mean	83.0	76.7	81.3	74.3	78.7
		SD	5.7	4.4	13.2	4.5	11.0
		Median	81.5	76.5	78.0	75.5	80.0
		Minimum	78	72	71	66	64
		Maximum	90	84	107	78	94

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-7.8		-4.6	-0.3
		SD	4.2		4.0	2.8
		Median	-7.0		-6.0	-0.5
		Minimum	-15		-8	-3
		Maximum	-3		2	3
Day 8		N	6	0	5	14
		Mean	78.2		74.4	77.6
		SD	6.8		6.0	5.6
		Median	76.5		74.0	77.0
		Minimum	70		68	71
		Maximum	89		84	92

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	6	6	6	6	6
	Mean	-0.8	3.5	4.2	-4.2	2.8
	SD	3.4	6.1	11.4	4.1	14.7
	Median	-1.0	2.5	2.5	-4.5	0.5
	Minimum	-5	-3	-9	-10	-17
	Maximum	3	13	25	2	22
Day 9	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	14
	Mean	-4.3		-6.4	-2.6
	SD	5.4		3.3	3.6
	Median	-4.5		-7.0	-2.5
	Minimum	-10		-10	-8
	Maximum	5		-3	7
Day 9	N	6	0	5	4
	Mean	78.2		76.2	82.5
	SD	7.0		4.3	7.5
	Median	77.5		76.0	83.0
	Minimum	69		71	75
	Maximum	89		81	89

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	-4.3		-4.6	1.0
	SD	6.0		8.7	3.8
	Median	-3.5		-7.0	2.0
	Minimum	-15		-14	-4
	Maximum	2		5	4
Day 15	N	6	0	5	4
	Mean	76.3		78.2	82.0
	SD	7.4		6.8	5.7
	Median	75.5		79.0	83.5
	Minimum	65		68	74
	Maximum	88		87	87

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	-6.2		-2.6	0.5
	SD	4.4		7.8	2.1
	Median	-7.0		-4.0	0.5
	Minimum	-10		-12	-2
	Maximum	1		8	3
Early Termination	N	0	3	1	0
	Mean		74.0	82.0	
	SD		2.6	.	
	Median		75.0	82.0	
	Minimum		71	82	
	Maximum		76	82	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Diastolic Blood Pressure (mmHg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	0	3	1	0
	Mean		-2.7	0.0	
	SD		4.6	.	
	Median		0.0	0.0	
	Minimum		-8	0	
	Maximum		0	0	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	66.8	66.7	68.5	63.0	64.0
	SD	8.8	10.8	9.9	11.0	10.3
	Median	66.5	68.5	70.0	62.5	64.5
	Minimum	57	49	51	47	46
	Maximum	79	78	79	80	77
Day 0	N	6	6	6	6	6
	Mean	66.3	71.8	69.8	75.0	69.5
	SD	8.5	15.3	9.7	21.7	18.9
	Median	65.0	66.5	73.0	69.0	68.0
	Minimum	57	56	56	57	46
	Maximum	80	100	80	116	99

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	72.5	68.3	66.5	67.5
	SD	3.4	11.4	7.4	10.5
	Median	72.0	66.5	64.5	65.0
	Minimum	69	57	58	56
	Maximum	77	90	76	97
Day 0	N	6	6	6	16
	Mean	71.8	62.7	63.8	65.2
	SD	8.8	14.5	3.7	10.7
	Median	73.0	56.0	65.0	65.0
	Minimum	58	52	58	49
	Maximum	84	90	67	94

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)			Treatment Group*				
			Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)
Day 1	Pre-dose	N	6	6	6	6	6
		Mean	76.5	74.0	73.0	73.7	67.5
		SD	14.1	15.9	7.9	12.3	6.3
		Median	69.5	75.5	74.0	72.5	68.0
		Minimum	65	55	60	60	59
		Maximum	99	97	83	93	75
Day 1	Post 0.5 hr	N	6	6	6	6	6
		Mean	77.2	68.7	68.8	68.5	64.8
		SD	12.1	12.0	9.5	9.0	11.5
		Median	71.0	68.5	69.5	66.5	66.5
		Minimum	65	54	56	60	47
		Maximum	93	88	81	85	79

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)			Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics						
Day 1	Pre-dose	N	6	6	6	16
		Mean	66.3	61.3	68.0	69.1
		SD	5.3	15.4	5.1	12.3
		Median	67.0	57.0	67.5	70.0
		Minimum	57	50	61	49
		Maximum	71	92	76	94
Day 1	Post 0.5 hr	N	6	6	6	16
		Mean	69.7	61.0	64.3	65.8
		SD	6.7	16.0	4.5	7.4
		Median	70.0	57.0	64.5	67.0
		Minimum	61	48	58	50
		Maximum	80	92	69	77

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 0.5 hr	N	6	6	6	6	6
		Mean	0.7	-5.3	-4.2	-5.2	-2.7
		SD	3.9	11.3	5.0	6.6	9.8
		Median	1.5	-5.0	-2.0	-6.0	-1.5
		Minimum	-6	-24	-13	-15	-15
		Maximum	4	8	1	4	13
Day 1	Post 1 hr	N	6	6	6	6	6
		Mean	72.2	73.7	68.0	75.5	64.5
		SD	4.3	14.6	11.2	14.1	9.0
		Median	70.0	69.5	68.0	71.5	62.0
		Minimum	69	58	51	60	54
		Maximum	79	101	80	101	80

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 0.5 hr	N	6	6	6	16
		Mean	3.3	-0.3	-3.7	-3.3
		SD	7.9	5.7	4.1	7.8
		Median	4.0	-1.0	-2.5	-2.0
		Minimum	-8	-8	-10	-28
		Maximum	15	9	1	4
Day 1	Post 1 hr	N	6	6	6	16
		Mean	72.2	62.2	68.2	65.8
		SD	9.6	16.0	12.0	7.8
		Median	76.5	58.0	63.5	66.0
		Minimum	60	48	59	52
		Maximum	81	91	89	76

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 1 hr	N	6	6	6	6	6
		Mean	-4.3	-0.3	-5.0	1.8	-3.0
		SD	10.7	9.4	9.1	16.6	8.6
		Median	-0.5	3.5	-4.5	-1.5	-2.5
		Minimum	-23	-14	-18	-13	-15
		Maximum	6	10	7	32	7
Day 1	Post 1.5 hrs	N	6	6	6	6	6
		Mean	74.0	71.8	70.8	76.0	60.7
		SD	9.9	14.1	7.9	10.6	7.2
		Median	71.0	71.5	71.0	70.5	62.5
		Minimum	62	54	60	69	47
		Maximum	87	91	80	96	68

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1 hr	N	6	6	6	16
		Mean	5.8	0.8	0.2	-3.3
		SD	8.5	6.3	11.0	9.0
		Median	7.0	-1.0	-1.5	-0.5
		Minimum	-9	-7	-11	-27
		Maximum	16	11	21	7
Day 1	Post 1.5 hrs	N	6	6	6	16
		Mean	69.2	61.2	63.7	67.9
		SD	7.1	14.2	5.0	9.2
		Median	68.5	55.0	64.0	65.5
		Minimum	61	50	55	54
		Maximum	78	88	69	85

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)			Treatment Group*				
			Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	6	6
		Mean	-2.5	-2.2	-2.2	2.3	-6.8
		SD	5.3	7.8	6.4	10.8	7.4
		Median	-1.5	0.5	-4.0	4.0	-7.5
		Minimum	-12	-16	-9	-13	-15
		Maximum	3	5	6	15	5
Day 1	Post 2 hrs	N	6	6	6	6	6
		Mean	68.8	72.5	69.5	71.2	63.2
		SD	7.4	12.1	9.2	5.1	9.8
		Median	70.5	72.0	72.0	73.0	65.0
		Minimum	60	59	57	63	45
		Maximum	80	90	78	76	75

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	16
		Mean	2.8	-0.2	-4.3	-1.1
		SD	6.7	3.8	3.7	12.8
		Median	3.5	-1.0	-4.5	-1.0
		Minimum	-8	-4	-9	-24
		Maximum	11	7	1	32
Day 1	Post 2 hrs	N	6	6	6	16
		Mean	71.2	60.0	64.3	66.8
		SD	8.7	16.2	5.6	8.8
		Median	69.0	53.5	63.5	69.5
		Minimum	63	50	56	50
		Maximum	86	92	72	79

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	6	6	6	6	6
		Mean	-7.7	-1.5	-3.5	-2.5	-4.3
		SD	11.8	9.0	7.1	8.8	8.3
		Median	-6.5	2.0	-4.0	0.0	-4.0
		Minimum	-28	-17	-13	-17	-17
		Maximum	4	7	9	6	6
Day 1	Post 4 hrs	N	6	6	6	6	6
		Mean	80.0	81.8	73.3	75.7	68.5
		SD	11.3	18.8	7.4	9.8	6.3
		Median	81.0	83.0	74.5	74.5	65.5
		Minimum	68	55	62	65	63
		Maximum	99	111	84	89	77

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	16
		Mean	4.8	-1.3	-3.7	-2.3
		SD	8.8	2.8	2.9	8.1
		Median	3.5	-0.5	-3.5	-1.5
		Minimum	-5	-6	-8	-24
		Maximum	21	2	1	12
Day 1	Post 4 hrs	N	6	6	6	16
		Mean	74.5	68.0	77.0	72.3
		SD	8.4	15.3	12.2	7.4
		Median	74.0	63.5	71.5	74.0
		Minimum	65	54	67	60
		Maximum	86	98	97	85

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 4 hrs	N	6	6	6	6	6
		Mean	3.5	7.8	0.3	2.0	1.0
		SD	12.1	8.9	3.5	9.1	3.2
		Median	6.5	8.5	0.0	4.5	2.0
		Minimum	-17	-3	-4	-10	-5
		Maximum	15	18	6	13	4
Day 1	Post 5 hrs	N	6	6	6	6	6
		Mean	73.5	77.3	69.2	74.2	71.3
		SD	7.0	11.7	9.1	12.2	8.9
		Median	72.0	79.0	70.5	78.0	71.0
		Minimum	66	62	53	57	56
		Maximum	86	89	80	86	82

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 4 hrs	N	6	6	6	16
		Mean	8.2	6.7	9.0	3.3
		SD	7.2	4.1	7.6	8.8
		Median	6.0	7.0	5.5	5.0
		Minimum	1	1	3	-16
		Maximum	21	13	21	14
Day 1	Post 5 hrs	N	6	6	6	16
		Mean	76.7	68.0	69.3	70.4
		SD	5.6	14.3	6.7	9.5
		Median	76.5	62.0	67.0	73.5
		Minimum	68	57	64	48
		Maximum	85	94	82	82

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 5 hrs	N	6	6	6	6	6
		Mean	-3.0	3.3	-3.8	0.5	3.8
		SD	12.6	14.7	3.9	15.1	6.2
		Median	-1.0	10.0	-4.0	0.0	4.5
		Minimum	-27	-21	-8	-19	-6
		Maximum	9	16	3	26	11
Day 1	Post 8 hrs	N	6	6	6	6	6
		Mean	76.0	70.0	68.0	68.7	69.7
		SD	9.3	10.3	9.0	9.4	10.7
		Median	74.5	71.0	63.0	67.0	66.0
		Minimum	63	57	61	56	62
		Maximum	89	84	80	80	91

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 5 hrs	N	6	6	6	16
		Mean	10.3	6.7	1.3	1.4
		SD	5.8	5.4	3.3	9.1
		Median	9.5	5.5	1.5	1.0
		Minimum	4	2	-3	-18
		Maximum	20	16	6	16
Day 1	Post 8 hrs	N	6	6	6	16
		Mean	71.2	65.7	80.7	70.9
		SD	8.3	10.9	12.9	8.3
		Median	72.0	62.5	79.5	70.0
		Minimum	60	54	66	56
		Maximum	81	86	101	84

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics							
Change from pre-dose	Post 8 hrs	N	6	6	6	6	6
		Mean	-0.5	-4.0	-5.0	-5.0	2.2
		SD	15.0	13.6	6.0	9.3	9.9
		Median	2.0	-0.5	-6.0	-1.0	-1.0
		Minimum	-28	-26	-11	-20	-8
		Maximum	17	11	2	3	18
Day 1	Post 12 hrs	N	6	6	6	5	6
		Mean	77.8	69.5	72.0	71.4	71.0
		SD	12.5	11.7	8.8	11.1	5.6
		Median	76.5	66.0	73.5	72.0	69.0
		Minimum	61	59	59	57	66
		Maximum	98	91	83	83	81

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 8 hrs	N	6	6	6	16
		Mean	4.8	4.3	12.7	1.9
		SD	11.1	5.5	8.2	7.1
		Median	2.0	5.5	12.0	4.0
		Minimum	-6	-6	1	-14
		Maximum	20	9	25	11
Day 1	Post 12 hrs	N	6	6	6	16
		Mean	76.5	67.3	77.5	75.1
		SD	4.2	9.8	11.3	5.6
		Median	76.0	66.0	74.5	75.0
		Minimum	71	55	65	62
		Maximum	84	85	94	82

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 12 hrs	N	6	6	6	5	6
		Mean	1.3	-4.5	-1.0	-5.0	3.5
		SD	14.9	10.2	5.3	9.3	5.1
		Median	6.5	-2.0	-0.5	0.0	5.0
		Minimum	-26	-21	-10	-19	-4
		Maximum	16	5	5	3	8
Day 2	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 12 hrs	N	6	6	6	16
		Mean	10.2	6.0	9.5	6.0
		SD	3.2	7.0	7.5	9.4
		Median	10.5	7.0	10.0	6.0
		Minimum	6	-7	0	-13
		Maximum	14	12	18	23
Day 2	Pre-dose	N	6	6	6	6
		Mean	73.2	65.7	70.8	60.2
		SD	7.5	20.8	7.4	7.1
		Median	73.0	59.5	69.0	58.5
		Minimum	64	46	63	51
		Maximum	82	106	82	70

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	6	6	6
		Mean	6.8	4.3	2.8	-1.7
		SD	7.3	6.1	3.3	5.9
		Median	9.0	5.0	3.5	1.0
		Minimum	-2	-4	-2	-11
		Maximum	15	14	6	3
Day 2	Post 2 hrs	N	6	6	6	6
		Mean	83.7	81.7	77.5	72.5
		SD	7.1	8.8	10.9	10.3
		Median	85.5	83.5	73.0	69.0
		Minimum	73	71	69	65
		Maximum	93	94	96	92

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 24 hrs	N	6	6	6	6	6
		Mean	83.2	77.3	65.5	84.0	71.7
		SD	11.5	8.9	8.7	11.1	13.3
		Median	83.5	76.5	65.0	86.5	70.0
		Minimum	65	68	53	65	57
		Maximum	98	92	77	94	95

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	6
		Mean	17.3	20.3	9.5	10.7
		SD	9.8	11.7	6.3	9.7
		Median	15.5	21.5	7.5	12.0
		Minimum	7	2	4	-6
		Maximum	30	34	20	21
Day 2	Post 24 hrs	N	0	0	0	10
		Mean				70.7
		SD				5.9
		Median				71.0
		Minimum				62
		Maximum				78

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 24 hrs	N	6	6	6	6	6
		Mean	6.7	3.3	-7.5	10.3	4.2
		SD	15.4	11.7	1.8	16.0	10.6
		Median	11.0	4.0	-8.0	10.0	0.0
		Minimum	-21	-14	-9	-8	-5
		Maximum	20	18	-5	34	22
Day 3	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 24 hrs	N	0	0	0	10
		Mean				-2.7
		SD				12.8
		Median				-4.0
		Minimum				-23
		Maximum				14
Day 3	Pre-dose	N	6	5	6	6
		Mean	75.2	65.2	73.7	68.5
		SD	7.1	7.0	13.4	10.0
		Median	77.0	66.0	71.0	65.0
		Minimum	63	55	61	60
		Maximum	82	73	97	85

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	5	6	6
		Mean	8.8	10.0	5.7	6.7
		SD	8.8	5.0	8.7	7.4
		Median	10.0	13.0	3.5	9.5
		Minimum	-2	4	-4	-7
		Maximum	23	14	21	12
Day 3	Post 2 hrs	N	6	4	6	6
		Mean	90.5	76.3	80.5	76.0
		SD	5.8	7.6	12.9	12.9
		Median	90.5	77.5	76.0	73.5
		Minimum	81	66	67	63
		Maximum	97	84	99	96

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 48 hrs	N	6	6	6	6	6
		Mean	86.2	77.5	74.7	78.0	76.0
		SD	11.7	12.1	7.6	13.5	9.1
		Median	89.5	77.0	75.0	79.0	75.5
		Minimum	67	65	66	60	65
		Maximum	97	93	83	97	89

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	4	6	6
		Mean	24.2	21.3	12.5	14.2
		SD	8.6	3.9	9.9	6.8
		Median	25.5	22.0	12.0	16.0
		Minimum	10	16	2	5
		Maximum	33	25	28	22
Day 3	Post 48 hrs	N	0	0	0	10
		Mean				77.4
		SD				9.4
		Median				79.5
		Minimum				64
		Maximum				93

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 48 hrs	N	6	6	6	6	6
		Mean	9.7	3.5	1.7	4.3	8.5
		SD	9.4	12.2	4.7	11.2	7.2
		Median	9.5	9.0	1.5	5.5	8.5
		Minimum	-3	-18	-6	-10	-1
		Maximum	20	13	7	16	16
Day 4	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 48 hrs	N	0	0	0	10
		Mean				4.0
		SD				11.1
		Median				5.0
		Minimum				-17
		Maximum				19
Day 4	Pre-dose	N	6	3	5	6
		Mean	76.2	65.3	73.4	63.8
		SD	9.6	6.4	17.7	7.3
		Median	77.0	68.0	67.0	63.5
		Minimum	62	58	64	56
		Maximum	87	70	105	76

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 4	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	3	5	6
		Mean	9.8	11.3	6.0	2.0
		SD	6.8	3.5	13.0	6.9
		Median	7.5	11.0	0.0	3.0
		Minimum	4	8	-1	-7
		Maximum	20	15	29	9
Day 4	Post 2 hrs	N	6	3	5	6
		Mean	95.3	77.3	77.0	83.5
		SD	4.0	16.2	7.3	11.5
		Median	96.5	80.0	75.0	84.5
		Minimum	90	60	69	65
		Maximum	99	92	88	97

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)			Treatment Group*				
			Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	3	5	6
		Mean	29.0	23.3	9.6	21.7
		SD	7.4	11.9	7.8	14.2
		Median	30.5	27.0	10.0	14.5
		Minimum	19	10	1	9
		Maximum	38	33	21	43
Day 5	Pre-dose	N	6	0	5	4
		Mean	76.8		71.6	66.8
		SD	8.2		11.1	5.7
		Median	76.0		69.0	65.0
		Minimum	67		63	62
		Maximum	89		91	75

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	10.5		4.2	7.3
		SD	10.7		6.5	7.9
		Median	6.5		2.0	7.5
		Minimum	1		-2	-2
		Maximum	24		15	16
Day 5	Post 2 hrs	N	6	0	5	4
		Mean	89.8		82.4	73.8
		SD	4.6		19.0	7.9
		Median	88.0		76.0	71.5
		Minimum	86		71	67
		Maximum	97		116	85

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	23.5		15.0	14.3
		SD	5.9		14.3	14.2
		Median	24.5		10.0	12.0
		Minimum	16		4	2
		Maximum	29		40	31
Day 6	Pre-dose	N	6	0	5	4
		Mean	74.3		73.0	64.0
		SD	9.1		10.7	7.4
		Median	73.0		71.0	65.0
		Minimum	63		65	55
		Maximum	91		91	71

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	8.0		5.6	4.5
		SD	9.1		7.5	11.1
		Median	5.0		3.0	5.5
		Minimum	1		-2	-10
		Maximum	26		15	17
Day 6	Post 2 hrs	N	6	0	5	4
		Mean	86.5		80.2	76.8
		SD	7.5		13.1	4.8
		Median	88.5		74.0	78.0
		Minimum	73		71	70
		Maximum	93		103	81

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)			Statistics	Treatment Group*				
				Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0	
		Mean						
		SD						
		Median						
		Minimum						
		Maximum						
Day 7	Pre-dose	N	0	0	0	0	0	
		Mean						
		SD						
		Median						
		Minimum						
		Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	20.2		12.8	17.3
		SD	9.7		8.8	8.2
		Median	19.5		12.0	19.0
		Minimum	8		3	6
		Maximum	35		27	25
Day 7	Pre-dose	N	6	0	5	4
		Mean	74.3		70.6	63.3
		SD	9.1		11.6	4.2
		Median	73.5		72.0	65.0
		Minimum	64		55	57
		Maximum	91		87	66

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	8.0		3.2	3.8
		SD	9.9		6.3	7.2
		Median	4.5		4.0	4.5
		Minimum	-1		-6	-5
		Maximum	26		11	11
Day 7	Post 2 hrs	N	6	0	5	4
		Mean	71.3		69.8	57.0
		SD	10.2		7.9	5.8
		Median	71.0		67.0	56.0
		Minimum	60		64	51
		Maximum	88		83	65

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 8		N	6	6	6	6	6
		Mean	68.8	71.3	74.0	66.7	67.0
		SD	9.8	11.3	13.7	2.6	13.4
		Median	67.5	67.5	75.5	67.0	66.5
		Minimum	56	61	55	64	46
		Maximum	83	88	92	71	88

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	5.0		2.4	-2.5
		SD	11.3		4.3	5.3
		Median	3.5		3.0	-2.0
		Minimum	-9		-3	-8
		Maximum	23		7	2
Day 8		N	6	0	5	14
		Mean	74.5		67.6	68.5
		SD	5.7		5.5	9.5
		Median	74.5		67.0	67.0
		Minimum	66		60	53
		Maximum	81		75	84

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	6	6	6	6	6
	Mean	-7.7	-2.7	1.0	-7.0	-0.5
	SD	15.2	12.4	9.3	10.8	11.3
	Median	-3.0	-3.0	2.0	-7.0	-0.5
	Minimum	-37	-21	-13	-22	-16
	Maximum	5	11	14	7	15
Day 9	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	14
	Mean	8.2		0.2	-0.9
	SD	7.9		4.8	10.8
	Median	10.5		-1.0	1.5
	Minimum	-3		-6	-22
	Maximum	16		7	15
Day 9	N	6	0	5	4
	Mean	73.5		73.6	64.5
	SD	3.8		5.3	1.7
	Median	74.0		73.0	65.0
	Minimum	67		67	62
	Maximum	78		81	66

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	7.2		6.2	5.0
	SD	4.8		4.4	10.1
	Median	7.5		6.0	4.5
	Minimum	1		0	-5
	Maximum	13		12	16
Day 15	N	6	0	5	4
	Mean	72.7		65.8	65.8
	SD	9.9		7.3	7.3
	Median	71.0		67.0	67.0
	Minimum	63		54	56
	Maximum	89		73	73

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	6.3		-1.6	6.3
	SD	10.1		7.0	11.4
	Median	5.5		2.0	8.5
	Minimum	-6		-11	-8
	Maximum	24		5	16
Early Termination	N	0	3	1	0
	Mean		76.3	73.0	
	SD		15.5	.	
	Median		76.0	73.0	
	Minimum		61	73	
	Maximum		92	73	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Pulse Rate (beats/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	0	3	1	0
	Mean		7.7	2.0	
	SD		10.8	.	
	Median		3.0	2.0	
	Minimum		0	2	
	Maximum		20	2	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	15.0	14.3	14.3	14.7	15.0
	SD	1.1	0.8	0.8	1.0	1.1
	Median	15.0	14.0	14.0	14.0	15.0
	Minimum	14	14	14	14	14
	Maximum	16	16	16	16	16
Day 0	N	6	6	6	6	6
	Mean	16.0	15.0	16.0	15.0	15.3
	SD	1.8	1.7	0.0	1.1	1.0
	Median	16.0	16.0	16.0	15.0	16.0
	Minimum	14	12	16	14	14
	Maximum	18	16	16	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Respiratory Rate (breaths/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	15.0	15.3	14.7	14.9
	SD	1.1	1.0	1.0	1.0
	Median	15.0	16.0	14.0	14.0
	Minimum	14	14	14	14
	Maximum	16	16	16	16
Day 0	N	6	6	6	16
	Mean	15.7	16.7	15.3	15.0
	SD	0.8	1.0	1.0	1.3
	Median	16.0	16.0	16.0	14.0
	Minimum	14	16	14	14
	Maximum	16	18	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Respiratory Rate (breaths/min)			Treatment Group*				
			Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)
Day 1	Pre-dose	N	6	6	6	6	6
		Mean	14.7	15.7	15.8	15.0	15.3
		SD	1.0	0.8	1.0	1.1	1.0
		Median	14.0	16.0	16.0	15.0	16.0
		Minimum	14	14	14	14	14
		Maximum	16	16	17	16	16
Day 1	Post 0.5 hr	N	6	6	6	6	6
		Mean	14.7	16.0	15.0	14.7	15.3
		SD	1.0	0.0	1.1	2.1	1.0
		Median	14.0	16.0	15.0	14.0	16.0
		Minimum	14	16	14	12	14
		Maximum	16	16	16	18	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1	Pre-dose	N	6	6	6	16
		Mean	15.3	14.7	14.7	14.8
		SD	1.0	1.0	1.0	1.2
		Median	16.0	14.0	14.0	14.0
		Minimum	14	14	14	12
		Maximum	16	16	16	16
Day 1	Post 0.5 hr	N	6	6	6	16
		Mean	15.3	13.3	14.7	15.3
		SD	1.0	1.0	1.6	1.4
		Median	16.0	14.0	15.0	16.0
		Minimum	14	12	12	12
		Maximum	16	14	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 0.5 hr	N	6	6	6	6	6
		Mean	0.0	0.3	-0.8	-0.3	0.0
		SD	1.3	0.8	1.0	2.9	1.3
		Median	0.0	0.0	-0.5	-1.0	0.0
		Minimum	-2	0	-2	-4	-2
		Maximum	2	2	0	4	2
Day 1	Post 1 hr	N	6	6	6	6	6
		Mean	19.0	16.2	14.3	15.7	15.3
		SD	1.1	0.4	0.8	0.8	1.0
		Median	19.0	16.0	14.0	16.0	16.0
		Minimum	18	16	14	14	14
		Maximum	20	17	16	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
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Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 0.5 hr	N	6	6	6	16
		Mean	0.0	-1.3	0.0	0.5
		SD	1.3	1.6	1.3	1.5
		Median	0.0	-1.0	0.0	0.0
		Minimum	-2	-4	-2	-2
		Maximum	2	0	2	4
Day 1	Post 1 hr	N	6	6	6	16
		Mean	14.7	14.3	14.3	15.3
		SD	2.1	0.8	0.8	1.2
		Median	14.0	14.0	14.0	16.0
		Minimum	12	14	14	14
		Maximum	18	16	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
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Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 1 hr	N	6	6	6	6	6
		Mean	4.3	0.5	-1.5	0.7	0.0
		SD	1.5	1.2	1.8	1.6	1.8
		Median	4.0	0.0	-2.0	1.0	0.0
		Minimum	2	0	-3	-2	-2
		Maximum	6	3	2	2	2
Day 1	Post 1.5 hrs	N	6	6	6	6	6
		Mean	17.3	16.0	15.7	14.7	14.3
		SD	1.6	0.0	1.4	1.6	2.3
		Median	17.0	16.0	16.0	15.0	14.0
		Minimum	16	16	14	12	12
		Maximum	20	16	17	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
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Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1 hr	N	6	6	6	16
		Mean	-0.7	-0.3	-0.3	0.5
		SD	2.1	0.8	1.5	1.7
		Median	-2.0	0.0	0.0	0.0
		Minimum	-2	-2	-2	-2
		Maximum	2	0	2	4
Day 1	Post 1.5 hrs	N	6	6	6	16
		Mean	16.0	16.0	15.3	15.8
		SD	1.3	1.8	1.0	1.2
		Median	16.0	16.0	16.0	16.0
		Minimum	14	14	14	14
		Maximum	18	18	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	6	6
		Mean	2.7	0.3	-0.2	-0.3	-1.0
		SD	2.1	0.8	1.8	2.3	2.8
		Median	2.0	0.0	0.0	0.0	-1.0
		Minimum	0	0	-2	-4	-4
		Maximum	6	2	3	2	2
Day 1	Post 2 hrs	N	6	6	6	6	6
		Mean	17.3	16.3	14.3	14.7	16.0
		SD	1.6	0.5	0.8	1.0	0.0
		Median	17.0	16.0	14.0	14.0	16.0
		Minimum	16	16	14	14	16
		Maximum	20	17	16	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 1.5 hrs	N	6	6	6	16
		Mean	0.7	1.3	0.7	1.0
		SD	1.6	2.4	1.6	1.3
		Median	1.0	1.0	1.0	0.0
		Minimum	-2	-2	-2	0
		Maximum	2	4	2	4
Day 1	Post 2 hrs	N	6	6	6	16
		Mean	14.7	14.3	16.0	15.5
		SD	1.6	1.5	0.0	1.7
		Median	15.0	14.0	16.0	16.0
		Minimum	12	12	16	12
		Maximum	16	16	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	6	6	6	6	6
		Mean	2.7	0.7	-1.5	-0.3	0.7
		SD	1.6	0.8	0.8	1.5	1.0
		Median	3.0	0.5	-2.0	0.0	0.0
		Minimum	0	0	-2	-2	0
		Maximum	4	2	0	2	2
Day 1	Post 4 hrs	N	6	6	6	6	6
		Mean	17.7	15.3	14.0	14.0	15.3
		SD	1.5	1.5	0.0	1.8	1.0
		Median	18.0	15.0	14.0	14.0	16.0
		Minimum	16	14	14	12	14
		Maximum	20	17	14	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	16
		Mean	-0.7	-0.3	1.3	0.8
		SD	1.6	1.5	1.0	1.9
		Median	-1.0	0.0	2.0	0.0
		Minimum	-2	-2	0	-2
		Maximum	2	2	2	6
Day 1	Post 4 hrs	N	6	6	6	16
		Mean	16.0	13.7	15.7	15.6
		SD	2.2	0.8	0.8	1.7
		Median	16.0	14.0	16.0	16.0
		Minimum	14	12	14	14
		Maximum	18	14	16	20

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 4 hrs	N	6	6	6	6	6
		Mean	3.0	-0.3	-1.8	-1.0	0.0
		SD	2.1	1.4	1.0	2.8	0.0
		Median	3.0	0.0	-2.0	-1.0	0.0
		Minimum	0	-2	-3	-4	0
		Maximum	6	1	0	2	0
Day 1	Post 5 hrs	N	6	6	6	6	6
		Mean	17.7	15.3	13.7	15.0	16.0
		SD	2.0	1.0	0.8	1.1	0.0
		Median	17.0	16.0	14.0	15.0	16.0
		Minimum	16	14	12	14	16
		Maximum	20	16	14	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 4 hrs	N	6	6	6	16
		Mean	0.7	-1.0	1.0	0.9
		SD	1.6	1.1	1.1	1.9
		Median	1.0	-1.0	1.0	1.0
		Minimum	-2	-2	0	-2
		Maximum	2	0	2	4
Day 1	Post 5 hrs	N	6	6	6	16
		Mean	16.0	15.0	15.7	15.5
		SD	2.5	1.1	0.8	1.9
		Median	17.0	15.0	16.0	16.0
		Minimum	12	14	14	12
		Maximum	18	16	16	20

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 5 hrs	N	6	6	6	6	6
		Mean	3.0	-0.3	-2.2	0.0	0.7
		SD	2.1	0.8	1.3	1.8	1.0
		Median	3.0	0.0	-2.0	0.0	0.0
		Minimum	0	-2	-4	-2	0
		Maximum	6	0	0	2	2
Day 1	Post 8 hrs	N	6	6	6	6	6
		Mean	17.3	14.7	15.7	14.0	15.0
		SD	2.4	1.6	1.5	1.8	2.1
		Median	17.0	15.0	16.0	14.0	15.0
		Minimum	14	12	14	12	12
		Maximum	20	16	18	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 5 hrs	N	6	6	6	16
		Mean	0.7	0.3	1.0	0.8
		SD	1.6	1.5	1.7	1.8
		Median	1.0	0.0	2.0	1.0
		Minimum	-2	-2	-2	-2
		Maximum	2	2	2	4
Day 1	Post 8 hrs	N	6	6	6	16
		Mean	15.0	15.3	14.7	15.0
		SD	1.1	1.0	1.6	2.1
		Median	15.0	16.0	15.0	14.0
		Minimum	14	14	12	12
		Maximum	16	16	16	20

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 8 hrs	N	6	6	6	6	6
		Mean	2.7	-1.0	-0.2	-1.0	-0.3
		SD	3.3	1.1	1.6	2.8	2.0
		Median	3.0	-1.0	0.0	-1.0	-1.0
		Minimum	-2	-2	-3	-4	-2
		Maximum	6	0	2	2	2
Day 1	Post 12 hrs	N	6	6	6	5	6
		Mean	17.0	15.7	15.7	16.8	16.3
		SD	1.1	0.8	0.8	1.8	1.5
		Median	17.0	16.0	16.0	16.0	16.0
		Minimum	16	14	14	16	14
		Maximum	18	16	16	20	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 8 hrs	N	6	6	6	16
		Mean	-0.3	0.7	0.0	0.3
		SD	2.0	1.0	1.3	2.0
		Median	-1.0	0.0	0.0	0.0
		Minimum	-2	0	-2	-4
		Maximum	2	2	2	4
Day 1	Post 12 hrs	N	6	6	6	16
		Mean	14.0	15.7	14.0	14.8
		SD	2.2	0.8	1.8	2.0
		Median	14.0	16.0	14.0	16.0
		Minimum	12	14	12	12
		Maximum	16	16	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 12 hrs	N	6	6	6	5	6
		Mean	2.3	0.0	-0.2	1.6	1.0
		SD	1.5	0.0	1.6	2.6	1.1
		Median	2.0	0.0	0.0	0.0	1.0
		Minimum	0	0	-3	0	0
		Maximum	4	0	2	6	2
Day 2	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 12 hrs	N	6	6	6	16
		Mean	-1.3	1.0	-0.7	0.0
		SD	2.4	1.1	2.1	2.1
		Median	-1.0	1.0	0.0	0.0
		Minimum	-4	0	-4	-4
		Maximum	2	2	2	4
Day 2	Pre-dose	N	6	6	6	6
		Mean	15.0	13.3	15.7	15.7
		SD	1.1	1.0	1.5	1.5
		Median	15.0	14.0	16.0	16.0
		Minimum	14	12	14	14
		Maximum	16	14	18	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	6	6	6
		Mean	-0.3	-1.3	1.0	1.3
		SD	1.5	1.0	1.7	2.1
		Median	0.0	-2.0	0.0	2.0
		Minimum	-2	-2	0	-2
		Maximum	2	0	4	4
Day 2	Post 2 hrs	N	6	6	6	6
		Mean	16.0	15.3	15.0	14.3
		SD	1.8	1.0	1.1	1.5
		Median	16.0	16.0	15.0	14.0
		Minimum	14	14	14	12
		Maximum	18	16	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 24 hrs	N	6	6	6	6	6
		Mean	15.7	14.8	15.0	15.0	15.7
		SD	0.8	1.3	1.1	1.1	0.8
		Median	16.0	14.0	15.0	15.0	16.0
		Minimum	14	14	14	14	14
		Maximum	16	17	16	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	6
		Mean	0.7	0.7	0.3	0.0
		SD	2.4	1.6	1.5	2.2
		Median	1.0	1.0	0.0	0.0
		Minimum	-2	-2	-2	-4
		Maximum	4	2	2	2
Day 2	Post 24 hrs	N	0	0	0	10
		Mean				14.8
		SD				1.0
		Median				14.0
		Minimum				14
		Maximum				16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 24 hrs	N	6	6	6	6	6
		Mean	1.0	-0.8	-0.8	0.0	0.3
		SD	1.1	1.3	1.6	1.3	0.8
		Median	1.0	-1.0	-1.5	0.0	0.0
		Minimum	0	-2	-2	-2	0
		Maximum	2	1	2	2	2
Day 3	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 24 hrs	N	0	0	0	10
		Mean				-0.2
		SD				1.1
		Median				0.0
		Minimum				-2
		Maximum				2
Day 3	Pre-dose	N	6	5	6	6
		Mean	15.7	14.0	15.8	15.7
		SD	0.8	1.4	1.8	1.5
		Median	16.0	14.0	15.5	16.0
		Minimum	14	12	14	14
		Maximum	16	16	18	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	5	6	6
		Mean	0.3	-0.8	1.2	1.3
		SD	0.8	1.1	2.2	2.1
		Median	0.0	0.0	0.0	2.0
		Minimum	0	-2	-1	-2
		Maximum	2	0	4	4
Day 3	Post 2 hrs	N	6	4	6	6
		Mean	16.0	14.0	14.3	14.3
		SD	1.3	1.6	2.3	0.8
		Median	16.0	14.0	14.0	14.0
		Minimum	14	12	12	14
		Maximum	18	16	18	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 48 hrs	N	6	6	6	6	6
		Mean	15.7	15.3	15.0	15.7	15.7
		SD	1.5	1.0	1.1	0.8	0.8
		Median	16.0	16.0	15.0	16.0	16.0
		Minimum	14	14	14	14	14
		Maximum	18	16	16	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	4	6	6
		Mean	0.7	-0.5	-0.3	0.0
		SD	2.1	1.0	2.7	1.3
		Median	0.0	0.0	0.0	0.0
		Minimum	-2	-2	-4	-2
		Maximum	4	0	4	2
Day 3	Post 48 hrs	N	0	0	0	10
		Mean				15.8
		SD				1.8
		Median				16.0
		Minimum				14
		Maximum				20

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 48 hrs	N	6	6	6	6	6
		Mean	1.0	-0.3	-0.8	0.7	0.3
		SD	1.7	0.8	1.0	1.0	1.5
		Median	2.0	0.0	-0.5	0.0	0.0
		Minimum	-2	-2	-2	0	-2
		Maximum	2	0	0	2	2
Day 4	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 48 hrs	N	0	0	0	10
		Mean				0.8
		SD				1.9
		Median				1.0
		Minimum				-2
		Maximum				4
Day 4	Pre-dose	N	6	3	5	6
		Mean	15.7	14.7	14.8	15.3
		SD	0.8	2.3	1.1	1.0
		Median	16.0	16.0	14.0	16.0
		Minimum	14	12	14	14
		Maximum	16	16	16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 4	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	3	5	6
		Mean	0.3	0.0	0.0	1.0
		SD	0.8	3.5	2.0	2.1
		Median	0.0	2.0	0.0	1.0
		Minimum	0	-4	-2	-2
		Maximum	2	2	2	4
Day 4	Post 2 hrs	N	6	3	5	6
		Mean	16.0	15.3	15.2	16.0
		SD	1.3	1.2	1.1	1.3
		Median	16.0	16.0	16.0	16.0
		Minimum	14	14	14	14
		Maximum	18	16	16	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	3	5	6
		Mean	0.7	0.7	0.4	1.7
		SD	2.1	2.3	1.7	2.3
		Median	0.0	2.0	0.0	2.0
		Minimum	-2	-2	-2	-2
		Maximum	4	2	2	4
Day 5	Pre-dose	N	6	0	5	4
		Mean	15.7		15.2	15.5
		SD	0.8		1.1	1.0
		Median	16.0		16.0	16.0
		Minimum	14		14	14
		Maximum	16		16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	0.3		0.4	1.5
		SD	0.8		0.9	1.9
		Median	0.0		0.0	1.0
		Minimum	0		0	0
		Maximum	2		2	4
Day 5	Post 2 hrs	N	6	0	5	4
		Mean	15.3		15.6	15.0
		SD	1.0		0.9	1.2
		Median	16.0		16.0	15.0
		Minimum	14		14	14
		Maximum	16		16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	0.0		0.8	1.0
		SD	0.0		1.1	2.6
		Median	0.0		0.0	1.0
		Minimum	0		0	-2
		Maximum	0		2	4
Day 6	Pre-dose	N	6	0	5	4
		Mean	15.7		15.6	15.0
		SD	1.5		0.9	1.2
		Median	16.0		16.0	15.0
		Minimum	14		14	14
		Maximum	18		16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	0.3		0.8	1.0
		SD	0.8		1.1	1.2
		Median	0.0		0.0	1.0
		Minimum	0		0	0
		Maximum	2		2	2
Day 6	Post 2 hrs	N	6	0	5	4
		Mean	16.0		16.0	15.0
		SD	0.0		1.4	1.2
		Median	16.0		16.0	15.0
		Minimum	16		14	14
		Maximum	16		18	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	0.7		1.2	1.0
		SD	1.0		1.1	1.2
		Median	0.0		2.0	1.0
		Minimum	0		0	0
		Maximum	2		2	2
Day 7	Pre-dose	N	6	0	5	4
		Mean	15.3		14.4	14.0
		SD	1.0		1.7	1.6
		Median	16.0		14.0	14.0
		Minimum	14		12	12
		Maximum	16		16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	0.0		-0.4	0.0
		SD	0.0		1.7	2.8
		Median	0.0		0.0	-1.0
		Minimum	0		-2	-2
		Maximum	0		2	4
Day 7	Post 2 hrs	N	6	0	5	4
		Mean	15.0		15.2	15.0
		SD	1.1		1.1	1.2
		Median	15.0		16.0	15.0
		Minimum	14		14	14
		Maximum	16		16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 8		N	6	6	6	6	6
		Mean	15.3	15.3	16.0	15.0	15.0
		SD	2.1	1.0	0.0	2.1	2.1
		Median	16.0	16.0	16.0	15.0	15.0
		Minimum	12	14	16	12	12
		Maximum	18	16	16	18	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-0.3		0.4	1.0
		SD	0.8		0.9	1.2
		Median	0.0		0.0	1.0
		Minimum	-2		0	0
		Maximum	0		2	2
Day 8		N	6	0	5	14
		Mean	14.3		14.0	14.4
		SD	1.5		0.0	1.9
		Median	14.0		14.0	14.0
		Minimum	12		14	12
		Maximum	16		14	18

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	6	6	6	6	6
	Mean	0.7	-0.3	0.2	0.0	-0.3
	SD	1.6	0.8	1.0	2.5	2.3
	Median	1.0	0.0	0.0	1.0	0.0
	Minimum	-2	-2	-1	-4	-4
	Maximum	2	0	2	2	2
Day 9	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	14
	Mean	-1.0		-0.8	-0.3
	SD	1.7		1.1	1.9
	Median	0.0		0.0	0.0
	Minimum	-4		-2	-4
	Maximum	0		0	2
Day 9	N	6	0	5	4
	Mean	15.7		14.8	14.0
	SD	0.8		1.1	0.0
	Median	16.0		14.0	14.0
	Minimum	14		14	14
	Maximum	16		16	14

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	0.3		0.0	0.0
	SD	1.5		0.0	1.6
	Median	0.0		0.0	0.0
	Minimum	-2		0	-2
	Maximum	2		0	2
Day 15	N	6	0	5	4
	Mean	15.0		15.6	15.0
	SD	1.1		0.9	1.2
	Median	15.0		16.0	15.0
	Minimum	14		14	14
	Maximum	16		16	16

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Respiratory Rate (breaths/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	-0.3		0.8	1.0
	SD	1.5		1.8	1.2
	Median	0.0		2.0	1.0
	Minimum	-2		-2	0
	Maximum	2		2	2
Early Termination	N	0	3	1	0
	Mean		14.7	18.0	
	SD		1.2	.	
	Median		14.0	18.0	
	Minimum		14	18	
	Maximum		16	18	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Respiratory Rate (breaths/min)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Respiratory Rate (breaths/min)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	0	3	1	0
	Mean		0.0	4.0	
	SD		2.0	.	
	Median		0.0	4.0	
	Minimum		-2	4	
	Maximum		2	4	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	36.70	36.77	36.65	36.63	36.65
	SD	0.14	0.10	0.10	0.10	0.20
	Median	36.70	36.80	36.65	36.60	36.70
	Minimum	36.5	36.6	36.5	36.5	36.3
	Maximum	36.9	36.9	36.8	36.8	36.8
Day 0	N	6	6	6	6	6
	Mean	36.85	37.02	36.85	36.85	36.77
	SD	0.23	0.21	0.21	0.27	0.23
	Median	36.80	37.00	36.85	36.80	36.70
	Minimum	36.5	36.8	36.6	36.5	36.5
	Maximum	37.1	37.3	37.1	37.2	37.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	36.85	36.87	36.82	36.79
	SD	0.20	0.12	0.15	0.15
	Median	36.75	36.85	36.85	36.75
	Minimum	36.7	36.7	36.6	36.6
	Maximum	37.1	37.0	37.0	37.2
Day 0	N	6	6	6	16
	Mean	36.75	36.80	36.77	36.71
	SD	0.15	0.23	0.18	0.15
	Median	36.75	36.80	36.75	36.70
	Minimum	36.6	36.5	36.5	36.4
	Maximum	37.0	37.1	37.0	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)			Statistics				
Day 1	Pre-dose	N	6	6	6	6	6
		Mean	36.80	37.03	36.93	36.63	36.73
		SD	0.17	0.26	0.10	0.15	0.15
		Median	36.80	37.00	36.90	36.60	36.70
		Minimum	36.5	36.7	36.8	36.5	36.5
		Maximum	37.0	37.5	37.1	36.9	36.9
Day 1	Post 0.5 hr	N	6	6	6	6	6
		Mean	36.67	36.92	36.77	36.78	36.60
		SD	0.12	0.23	0.21	0.17	0.24
		Median	36.60	36.85	36.80	36.80	36.55
		Minimum	36.6	36.7	36.4	36.5	36.3
		Maximum	36.9	37.2	37.0	37.0	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1	Pre-dose	N	6	6	6	16
		Mean	36.73	36.80	36.78	36.75
		SD	0.23	0.34	0.13	0.14
		Median	36.75	36.80	36.80	36.80
		Minimum	36.5	36.3	36.6	36.6
		Maximum	37.1	37.3	36.9	37.1
Day 1	Post 0.5 hr	N	6	6	6	16
		Mean	36.63	36.75	36.78	36.78
		SD	0.16	0.20	0.20	0.16
		Median	36.65	36.70	36.80	36.80
		Minimum	36.4	36.6	36.5	36.5
		Maximum	36.8	37.1	37.0	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)	Change from pre-dose	N	6	6	6	6	6
		Mean	-0.13	-0.12	-0.17	0.15	-0.13
		SD	0.14	0.19	0.16	0.12	0.31
		Median	-0.15	-0.15	-0.15	0.10	-0.10
		Minimum	-0.3	-0.3	-0.4	0.0	-0.6
		Maximum	0.1	0.2	0.0	0.3	0.3
Day 1	Post 1 hr	N	6	6	6	6	6
		Mean	36.65	36.83	36.78	36.68	36.73
		SD	0.23	0.08	0.23	0.17	0.32
		Median	36.65	36.85	36.80	36.65	36.80
		Minimum	36.4	36.7	36.4	36.5	36.3
		Maximum	37.0	36.9	37.1	37.0	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 0.5 hr	N	6	6	6	16
		Mean	-0.10	-0.05	0.00	0.03
		SD	0.17	0.27	0.11	0.16
		Median	-0.05	0.00	-0.00	0.10
		Minimum	-0.3	-0.5	-0.1	-0.3
		Maximum	0.1	0.3	0.1	0.2
Day 1	Post 1 hr	N	6	6	6	16
		Mean	36.77	36.65	36.82	36.77
		SD	0.23	0.27	0.17	0.14
		Median	36.75	36.60	36.85	36.75
		Minimum	36.5	36.3	36.5	36.5
		Maximum	37.1	37.1	37.0	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)	Change from pre-dose	N	6	6	6	6	6
		Mean	-0.15	-0.20	-0.15	0.05	0.00
		SD	0.16	0.24	0.19	0.05	0.36
		Median	-0.10	-0.15	-0.15	0.05	-0.00
		Minimum	-0.4	-0.6	-0.4	0.0	-0.6
		Maximum	0.0	0.1	0.1	0.1	0.4
Day 1	Post 1.5 hrs	N	6	6	6	6	6
		Mean	36.60	36.88	36.75	36.80	36.80
		SD	0.20	0.16	0.24	0.28	0.30
		Median	36.60	36.90	36.80	36.65	36.90
		Minimum	36.4	36.7	36.3	36.6	36.4
		Maximum	36.9	37.1	37.0	37.2	37.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 1 hr	N	6	6	6	16
		Mean	0.03	-0.15	0.03	0.02
		SD	0.18	0.29	0.08	0.15
		Median	0.05	-0.05	0.05	0.05
		Minimum	-0.2	-0.7	-0.1	-0.4
		Maximum	0.3	0.1	0.1	0.2
Day 1	Post 1.5 hrs	N	6	6	6	16
		Mean	36.72	36.63	36.73	36.73
		SD	0.23	0.15	0.19	0.17
		Median	36.75	36.60	36.75	36.75
		Minimum	36.4	36.5	36.4	36.4
		Maximum	37.0	36.9	36.9	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Post 1.5 hrs	N	6	6	6	6	6
		Mean	-0.20	-0.15	-0.18	0.17	0.07
		SD	0.15	0.22	0.19	0.21	0.37
		Median	-0.20	-0.10	-0.15	0.10	0.10
		Minimum	-0.4	-0.5	-0.5	-0.1	-0.4
		Maximum	0.0	0.1	0.0	0.5	0.5
Day 1	Post 2 hrs	N	6	6	6	6	6
		Mean	36.67	36.80	36.85	36.67	36.63
		SD	0.15	0.25	0.27	0.08	0.22
		Median	36.70	36.80	36.90	36.65	36.65
		Minimum	36.4	36.4	36.4	36.6	36.3
		Maximum	36.8	37.1	37.2	36.8	36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 1.5 hrs	N	6	6	6	16
		Mean	-0.02	-0.17	-0.05	-0.02
		SD	0.15	0.34	0.12	0.16
		Median	-0.05	-0.10	0.00	0.00
		Minimum	-0.2	-0.8	-0.2	-0.4
		Maximum	0.2	0.2	0.1	0.3
Day 1	Post 2 hrs	N	6	6	6	16
		Mean	36.75	36.70	36.75	36.76
		SD	0.24	0.15	0.19	0.21
		Median	36.75	36.70	36.80	36.70
		Minimum	36.4	36.5	36.4	36.4
		Maximum	37.1	36.9	36.9	37.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)	Change from Pre-dose	N	6	6	6	6	6
		Mean	-0.13	-0.23	-0.08	0.03	-0.10
		SD	0.08	0.15	0.22	0.08	0.30
		Median	-0.15	-0.30	-0.10	0.05	-0.05
		Minimum	-0.2	-0.4	-0.4	-0.1	-0.6
		Maximum	0.0	0.0	0.2	0.1	0.2
Day 1	Post 4 hrs	N	6	6	6	6	6
		Mean	36.65	36.83	36.98	36.72	36.87
		SD	0.20	0.15	0.15	0.12	0.22
		Median	36.60	36.80	36.95	36.70	36.95
		Minimum	36.4	36.7	36.8	36.6	36.6
		Maximum	37.0	37.0	37.2	36.9	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)	Change from pre-dose	Post 2 hrs				
		N	6	6	6	16
		Mean	0.02	-0.10	-0.03	0.01
		SD	0.30	0.38	0.14	0.19
		Median	0.10	-0.10	-0.05	0.00
		Minimum	-0.4	-0.7	-0.2	-0.4
		Maximum	0.3	0.5	0.2	0.4
Day 1	Post 4 hrs	N	6	6	6	16
		Mean	36.75	36.70	36.78	36.76
		SD	0.19	0.09	0.17	0.15
		Median	36.80	36.70	36.80	36.70
		Minimum	36.4	36.6	36.5	36.5
		Maximum	36.9	36.8	37.0	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)	Change from Pre-dose	N	6	6	6	6	6
		Mean	-0.15	-0.20	0.05	0.08	0.13
		SD	0.10	0.20	0.15	0.12	0.27
		Median	-0.15	-0.20	0.05	0.05	0.25
		Minimum	-0.3	-0.5	-0.2	0.0	-0.3
		Maximum	0.0	0.0	0.2	0.3	0.4
Day 1	Post 5 hrs	N	6	6	6	6	6
		Mean	36.67	36.88	36.93	36.65	36.88
		SD	0.12	0.17	0.25	0.10	0.19
		Median	36.65	36.85	37.00	36.65	36.90
		Minimum	36.5	36.7	36.5	36.5	36.6
		Maximum	36.8	37.2	37.2	36.8	37.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 4 hrs	N	6	6	6	16
		Mean	0.02	-0.10	0.00	0.01
		SD	0.18	0.36	0.20	0.20
		Median	0.10	-0.15	-0.10	0.00
		Minimum	-0.3	-0.6	-0.2	-0.6
		Maximum	0.2	0.5	0.3	0.3
Day 1	Post 5 hrs	N	6	6	6	16
		Mean	36.80	36.75	36.93	36.78
		SD	0.15	0.16	0.18	0.20
		Median	36.80	36.80	36.85	36.75
		Minimum	36.6	36.5	36.8	36.5
		Maximum	37.0	36.9	37.2	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Post 5 hrs	N	6	6	6	6	6
		Mean	-0.13	-0.15	0.00	0.02	0.15
		SD	0.08	0.10	0.24	0.19	0.29
		Median	-0.15	-0.15	0.05	0.05	0.15
		Minimum	-0.2	-0.3	-0.4	-0.2	-0.3
		Maximum	0.0	0.0	0.3	0.3	0.5
Day 1	Post 8 hrs	N	6	6	6	6	6
		Mean	36.80	36.90	37.02	36.72	36.88
		SD	0.17	0.11	0.15	0.15	0.17
		Median	36.85	36.90	37.05	36.65	36.90
		Minimum	36.6	36.7	36.8	36.6	36.6
		Maximum	37.0	37.0	37.2	36.9	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 5 hrs	N	6	6	6	16
		Mean	0.07	-0.05	0.15	0.03
		SD	0.18	0.45	0.21	0.22
		Median	0.15	0.00	0.15	0.05
		Minimum	-0.2	-0.8	-0.1	-0.4
		Maximum	0.2	0.6	0.5	0.3
Day 1	Post 8 hrs	N	6	6	6	16
		Mean	36.87	36.87	36.85	36.86
		SD	0.20	0.15	0.08	0.17
		Median	36.80	36.80	36.90	36.85
		Minimum	36.7	36.7	36.7	36.6
		Maximum	37.2	37.1	36.9	37.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)	Change from Pre-dose	N	6	6	6	6	6
		Mean	0.00	-0.13	0.08	0.08	0.15
		SD	0.22	0.19	0.13	0.15	0.29
		Median	0.10	-0.10	0.10	0.05	0.25
		Minimum	-0.4	-0.5	-0.1	-0.1	-0.3
		Maximum	0.2	0.0	0.2	0.3	0.4
Day 1	Post 12 hrs	N	6	6	6	5	6
		Mean	36.80	36.80	36.97	36.72	36.88
		SD	0.06	0.24	0.12	0.11	0.15
		Median	36.80	36.80	36.90	36.70	36.95
		Minimum	36.7	36.4	36.9	36.6	36.7
		Maximum	36.9	37.1	37.2	36.9	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)	Change from pre-dose	Post 8 hrs				
		N	6	6	6	16
		Mean	0.13	0.07	0.07	0.11
		SD	0.20	0.26	0.08	0.15
		Median	0.10	0.05	0.05	0.10
		Minimum	-0.1	-0.3	0.0	-0.2
		Maximum	0.4	0.5	0.2	0.4
Day 1	Post 12 hrs	N	6	6	6	16
		Mean	36.92	36.93	36.80	36.88
		SD	0.20	0.19	0.18	0.20
		Median	36.95	37.00	36.85	36.90
		Minimum	36.7	36.7	36.5	36.6
		Maximum	37.1	37.1	37.0	37.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 12 hrs	N	6	6	6	5	6
		Mean	0.00	-0.23	0.03	0.10	0.15
		SD	0.14	0.20	0.15	0.10	0.26
		Median	0.00	-0.25	0.00	0.10	0.15
		Minimum	-0.2	-0.5	-0.2	0.0	-0.2
		Maximum	0.2	0.1	0.2	0.2	0.5
Day 2	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 12 hrs	N	6	6	6	16
		Mean	0.18	0.13	0.02	0.13
		SD	0.12	0.31	0.12	0.17
		Median	0.20	0.10	0.00	0.10
		Minimum	0.0	-0.2	-0.1	-0.2
		Maximum	0.3	0.7	0.2	0.4
Day 2	Pre-dose	N	6	6	6	6
		Mean	36.65	36.85	36.80	36.80
		SD	0.15	0.19	0.15	0.11
		Median	36.65	36.80	36.80	36.80
		Minimum	36.4	36.7	36.6	36.7
		Maximum	36.8	37.2	37.0	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Pre-dose	N	6	6	6	6
		Mean	-0.08	0.05	0.02	0.07
		SD	0.13	0.30	0.04	0.12
		Median	-0.10	0.05	0.00	0.05
		Minimum	-0.3	-0.4	0.0	-0.1
		Maximum	0.1	0.5	0.1	0.2
Day 2	Post 2 hrs	N	6	6	6	6
		Mean	36.87	36.85	36.78	36.80
		SD	0.33	0.27	0.22	0.13
		Median	36.75	36.85	36.70	36.85
		Minimum	36.6	36.5	36.5	36.6
		Maximum	37.5	37.2	37.1	36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 2	Post 24 hrs	N	6	6	6	6	6
		Mean	36.73	36.80	36.85	36.75	36.78
		SD	0.08	0.20	0.31	0.12	0.24
		Median	36.70	36.80	36.90	36.80	36.85
		Minimum	36.7	36.5	36.5	36.6	36.5
		Maximum	36.9	37.0	37.3	36.9	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	6	6	6
		Mean	0.13	0.05	0.00	0.07
		SD	0.19	0.38	0.14	0.18
		Median	0.10	0.15	0.00	0.05
		Minimum	-0.1	-0.5	-0.2	-0.2
		Maximum	0.4	0.5	0.2	0.3
Day 2	Post 24 hrs	N	0	0	0	10
		Mean				36.68
		SD				0.19
		Median				36.70
		Minimum				36.4
		Maximum				36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 24 hrs	N	6	6	6	6	6
		Mean	-0.07	-0.23	-0.08	0.12	0.05
		SD	0.19	0.23	0.26	0.12	0.32
		Median	-0.10	-0.20	-0.10	0.10	0.05
		Minimum	-0.3	-0.5	-0.4	0.0	-0.4
		Maximum	0.2	0.0	0.3	0.3	0.4
Day 3	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 24 hrs	N	0	0	0	10
		Mean				-0.08
		SD				0.17
		Median				-0.05
		Minimum				-0.4
		Maximum				0.1
Day 3	Pre-dose	N	6	5	6	6
		Mean	36.80	36.72	36.80	36.73
		SD	0.18	0.13	0.28	0.10
		Median	36.85	36.70	36.80	36.70
		Minimum	36.5	36.6	36.5	36.6
		Maximum	37.0	36.9	37.2	36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Pre-dose	N	6	5	6	6
		Mean	0.07	-0.04	0.02	0.00
		SD	0.22	0.27	0.17	0.06
		Median	0.05	0.00	0.00	0.00
		Minimum	-0.2	-0.4	-0.2	-0.1
		Maximum	0.4	0.3	0.3	0.1
Day 3	Post 2 hrs	N	6	4	6	6
		Mean	36.85	36.83	36.80	36.87
		SD	0.31	0.10	0.15	0.10
		Median	36.75	36.85	36.85	36.90
		Minimum	36.5	36.7	36.5	36.7
		Maximum	37.4	36.9	36.9	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 3	Post 48 hrs	N	6	6	6	6	6
		Mean	36.65	36.90	36.97	36.67	36.73
		SD	0.10	0.26	0.32	0.10	0.23
		Median	36.65	36.95	37.00	36.60	36.75
		Minimum	36.5	36.5	36.6	36.6	36.5
		Maximum	36.8	37.2	37.4	36.8	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Protocol: LB-102-001

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)	Change from pre-dose	Post 2 hrs				
		N	6	4	6	6
		Mean	0.12	0.20	0.02	0.13
		SD	0.26	0.26	0.08	0.05
		Median	0.00	0.20	0.00	0.10
		Minimum	-0.1	-0.1	-0.1	0.1
		Maximum	0.6	0.5	0.1	0.2
Day 3	Post 48 hrs	N	0	0	0	10
		Mean				36.80
		SD				0.26
		Median				36.80
		Minimum				36.5
		Maximum				37.3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 48 hrs	N	6	6	6	6	6
		Mean	-0.15	-0.13	0.03	0.03	0.00
		SD	0.20	0.34	0.25	0.12	0.32
		Median	-0.10	-0.10	0.10	0.05	0.15
		Minimum	-0.5	-0.5	-0.3	-0.1	-0.4
		Maximum	0.1	0.2	0.4	0.2	0.3
Day 4	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 48 hrs	N	0	0	0	10
		Mean				0.04
		SD				0.25
		Median				0.00
		Minimum				-0.3
		Maximum				0.5
Day 4	Pre-dose	N	6	3	5	6
		Mean	36.70	36.80	36.68	36.78
		SD	0.24	0.20	0.13	0.10
		Median	36.65	36.80	36.60	36.80
		Minimum	36.5	36.6	36.6	36.6
		Maximum	37.1	37.0	36.9	36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 4	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Pre-dose	N	6	3	5	6
		Mean	-0.03	0.07	-0.12	0.05
		SD	0.08	0.12	0.16	0.08
		Median	0.00	0.00	0.00	0.00
		Minimum	-0.2	0.0	-0.3	0.0
		Maximum	0.0	0.2	0.0	0.2
Day 4	Post 2 hrs	N	6	3	5	6
		Mean	36.80	36.87	36.78	36.83
		SD	0.18	0.15	0.13	0.12
		Median	36.75	36.90	36.80	36.85
		Minimum	36.6	36.7	36.6	36.7
		Maximum	37.1	37.0	36.9	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 2 hrs	N	6	3	5	6
		Mean	0.07	0.13	-0.02	0.10
		SD	0.10	0.06	0.11	0.17
		Median	0.10	0.10	0.00	0.05
		Minimum	-0.1	0.1	-0.2	-0.1
		Maximum	0.2	0.2	0.1	0.3
Day 5	Pre-dose	N	6	0	5	4
		Mean	36.75		36.84	36.73
		SD	0.19		0.13	0.10
		Median	36.75		36.90	36.75
		Minimum	36.5		36.7	36.6
		Maximum	37.0		37.0	36.8

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 5	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	0.02		0.04	0.00
		SD	0.15		0.05	0.08
		Median	0.05		0.00	0.00
		Minimum	-0.2		0.0	-0.1
		Maximum	0.2		0.1	0.1
Day 5	Post 2 hrs	N	6	0	5	4
		Mean	36.77		36.78	36.93
		SD	0.15		0.15	0.29
		Median	36.80		36.80	36.85
		Minimum	36.6		36.6	36.7
		Maximum	37.0		37.0	37.3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	0.03		-0.02	0.20
		SD	0.18		0.13	0.22
		Median	0.10		0.00	0.15
		Minimum	-0.3		-0.2	0.0
		Maximum	0.2		0.1	0.5
Day 6	Pre-dose	N	6	0	5	4
		Mean	36.72		36.78	36.78
		SD	0.23		0.11	0.10
		Median	36.65		36.80	36.75
		Minimum	36.5		36.6	36.7
		Maximum	37.0		36.9	36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 6	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-0.02		-0.02	0.05
		SD	0.15		0.08	0.06
		Median	-0.05		0.00	0.05
		Minimum	-0.2		-0.1	0.0
		Maximum	0.2		0.1	0.1
Day 6	Post 2 hrs	N	6	0	5	4
		Mean	36.83		36.88	37.00
		SD	0.16		0.23	0.18
		Median	36.85		36.80	37.00
		Minimum	36.6		36.6	36.8
		Maximum	37.0		37.2	37.2

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Temperature (C)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	0.10		0.08	0.28
		SD	0.23		0.25	0.10
		Median	0.05		0.00	0.25
		Minimum	-0.1		-0.1	0.2
		Maximum	0.5		0.5	0.4
Day 7	Pre-dose	N	6	0	5	4
		Mean	36.70		36.72	36.85
		SD	0.21		0.13	0.21
		Median	36.65		36.70	36.85
		Minimum	36.5		36.6	36.6
		Maximum	37.0		36.9	37.1

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)							
Change from pre-dose	Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 7	Post 2 hrs	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Temperature (C)						
Change from pre-dose	Pre-dose	N	6	0	5	4
		Mean	-0.03		-0.08	0.13
		SD	0.12		0.08	0.17
		Median	-0.05		-0.10	0.15
		Minimum	-0.2		-0.2	-0.1
		Maximum	0.1		0.0	0.3
Day 7	Post 2 hrs	N	6	0	5	4
		Mean	36.67		36.74	36.88
		SD	0.34		0.11	0.13
		Median	36.65		36.70	36.90
		Minimum	36.3		36.6	36.7
		Maximum	37.1		36.9	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Temperature (C)	Change from Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
Day 8		N	6	6	6	6	6
		Mean	36.65	36.65	36.70	36.62	36.47
		SD	0.24	0.24	0.24	0.15	0.14
		Median	36.65	36.60	36.80	36.65	36.45
		Minimum	36.4	36.4	36.4	36.4	36.3
		Maximum	36.9	37.1	36.9	36.8	36.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	Post 2 hrs	N	6	0	5	4
		Mean	-0.07		-0.06	0.15
		SD	0.27		0.09	0.13
		Median	-0.05		0.00	0.15
		Minimum	-0.5		-0.2	0.0
		Maximum	0.3		0.0	0.3
Day 8		N	6	0	5	14
		Mean	36.73		36.74	36.69
		SD	0.14		0.15	0.17
		Median	36.75		36.80	36.70
		Minimum	36.5		36.5	36.3
		Maximum	36.9		36.9	36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	6	6	6	6	6
	Mean	-0.15	-0.38	-0.23	-0.02	-0.27
	SD	0.16	0.39	0.22	0.19	0.12
	Median	-0.10	-0.35	-0.15	-0.05	-0.20
	Minimum	-0.4	-1.0	-0.5	-0.3	-0.5
	Maximum	0.0	0.1	0.0	0.2	-0.2
Day 9	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	14
	Mean	0.00		-0.06	-0.06
	SD	0.21		0.24	0.24
	Median	0.05		0.00	0.00
	Minimum	-0.4		-0.4	-0.6
	Maximum	0.2		0.2	0.3
Day 9	N	6	0	5	4
	Mean	36.78		36.72	36.80
	SD	0.16		0.19	0.08
	Median	36.80		36.70	36.80
	Minimum	36.5		36.5	36.7
	Maximum	37.0		37.0	36.9

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	0.05		-0.08	0.07
	SD	0.21		0.15	0.05
	Median	0.05		-0.10	0.10
	Minimum	-0.3		-0.3	0.0
	Maximum	0.3		0.1	0.1
Day 15	N	6	0	5	4
	Mean	36.75		36.80	36.85
	SD	0.22		0.25	0.13
	Median	36.80		36.80	36.85
	Minimum	36.5		36.5	36.7
	Maximum	37.0		37.2	37.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	0.02		0.00	0.13
	SD	0.35		0.26	0.15
	Median	0.05		0.10	0.10
	Minimum	-0.6		-0.4	0.0
	Maximum	0.4		0.3	0.3
Early Termination	N	0	3	1	0
	Mean		36.70	36.80	
	SD		0.20	.	
	Median		36.70	36.80	
	Minimum		36.5	36.8	
	Maximum		36.9	36.8	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Temperature (C)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	0	3	1	0
	Mean		-0.17	0.10	
	SD		0.60	.	
	Median		-0.10	0.10	
	Minimum		-0.8	0.1	
	Maximum		0.4	0.1	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Body Mass Index (kg/m <sup>2</sup> )	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	25.7	23.9	25.3	24.2	24.3
	SD	3.2	3.1	4.2	3.3	2.1
	Median	26.1	23.6	25.0	24.3	24.4
	Minimum	20	21	21	20	21
	Maximum	30	28	30	28	27

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Body Mass Index (kg/m <sup>2</sup> )	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	26.0	22.8	24.1	25.1
	SD	2.5	3.1	2.0	2.4
	Median	26.1	22.9	23.4	24.5
	Minimum	23	19	22	22
	Maximum	30	27	28	30

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Height (cm)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	166.8	168.5	183.0	171.7	174.9
	SD	7.5	8.8	10.0	7.3	6.6
	Median	166.6	169.4	188.5	169.1	175.8
	Minimum	159	157	168	164	163
	Maximum	180	178	191	182	182

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.1 - Vital Signs

Height (cm)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	174.5	175.2	170.6	172.6
	SD	3.3	7.8	11.0	9.5
	Median	175.0	173.1	173.3	173.7
	Minimum	169	168	157	154
	Maximum	178	190	182	187

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	72.1	68.7	85.0	71.2	74.5
	SD	13.5	15.7	18.0	6.4	7.8
	Median	70.8	66.0	80.5	71.0	74.2
	Minimum	57	51	61	64	63
	Maximum	97	87	107	81	85
Day 8	N	6	6	6	6	6
	Mean	72.3	69.2	85.1	71.6	75.8
	SD	13.1	16.7	16.5	5.6	7.4
	Median	71.4	66.3	77.7	72.0	74.5
	Minimum	56	49	69	65	66
	Maximum	95	89	106	80	85

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	79.4	69.9	70.1	75.3
	SD	8.6	6.8	8.4	11.2
	Median	80.1	71.3	71.9	76.8
	Minimum	66	60	59	52
	Maximum	91	79	82	93
Day 8	N	0	0	0	10
	Mean				75.1
	SD				13.5
	Median				77.8
	Minimum				51
	Maximum				94

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

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Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	6	6	6	6	6
	Mean	0.3	0.5	0.1	0.4	1.3
	SD	1.5	1.5	3.7	1.2	1.3
	Median	0.6	0.8	-0.4	0.4	1.0
	Minimum	-2	-2	-3	-1	-1
	Maximum	2	2	7	2	3
Day 15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas

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Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	0	0	0	10
	Mean				0.2
	SD				1.3
	Median				0.1
	Minimum				-3
	Maximum				2
Day 15	N	6	0	5	4
	Mean	79.4		70.0	80.1
	SD	9.3		9.9	3.2
	Median	79.8		71.6	80.3
	Minimum	65		59	77
	Maximum	93		83	83

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.1.vs.sas



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Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Early Termination	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	6	0	5	4
	Mean	0.0		0.6	0.6
	SD	0.9		0.9	0.9
	Median	-0.1		0.5	0.3
	Minimum	-1		-1	-0
	Maximum	2		2	2
Early Termination	N	0	3	0	0
	Mean		67.6		
	SD		7.2		
	Median		71.5		
	Minimum		59		
	Maximum		72		

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.1 - Vital Signs

Weight (kg)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from pre-dose	N	0	3	0	0
	Mean		0.1		
	SD		0.8		
	Median		0.4		
	Minimum		-1		
	Maximum		1		

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Statistics						
Day -28 to -1	N	6	6	6	6	6
	Mean	60.0	60.0	60.7	64.3	61.6
	SD	4.9	6.5	14.4	11.7	10.3
	Median	58.5	61.5	58.0	63.5	65.8
	Minimum	56.0	50.0	43.0	48.0	41.7
	Maximum	69.0	66.0	82.0	81.0	68.7
Day 0	N	6	6	6	6	6
	Mean	61.2	68.7	61.7	63.8	62.8
	SD	4.1	15.4	12.2	4.4	9.9
	Median	60.0	64.5	63.5	63.0	65.2
	Minimum	57.0	53.0	41.0	59.0	45.7
	Maximum	69.0	93.0	76.0	70.0	71.3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Day -28 to -1	N	6	6	6	16
	Mean	66.5	63.2	59.1	62.3
	SD	4.6	12.5	2.9	7.7
	Median	68.0	59.3	59.2	60.0
	Minimum	58.3	54.0	56.0	51.0
	Maximum	70.0	88.3	63.3	79.7
Day 0	N	6	6	6	16
	Mean	68.5	61.7	58.1	60.8
	SD	8.2	12.6	6.4	7.2
	Median	69.0	55.2	58.8	58.2
	Minimum	57.3	54.3	48.0	52.7
	Maximum	77.3	86.0	64.7	75.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Pre-dose	N	6	6	6	6	6
	Mean	64.8	61.7	59.5	59.5	61.1
	SD	8.0	10.5	10.7	10.2	10.1
	Median	63.0	60.0	61.0	56.0	64.5
	Minimum	56.0	52.0	41.0	51.0	43.7
	Maximum	79.0	80.0	70.0	79.0	71.0
Day 1: Post 1 hr	N	0	0	0	0	6
	Mean					58.2
	SD					9.7
	Median					58.7
	Minimum					42.0
	Maximum					70.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Day 1: Pre-dose	N	6	6	6	16
	Mean	61.6	56.4	59.3	62.0
	SD	6.0	9.4	7.0	9.0
	Median	61.3	52.2	57.3	62.5
	Minimum	51.3	51.0	52.0	47.0
	Maximum	67.7	75.0	68.7	75.0
Day 1: Post 1 hr	N	6	6	6	8
	Mean	62.5	54.6	57.8	59.0
	SD	6.9	10.3	6.2	7.7
	Median	62.2	51.5	58.0	58.3
	Minimum	54.7	45.7	48.3	50.0
	Maximum	74.7	75.0	64.7	70.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	Statistics					
	N	0	0	0	0	6
	Mean					-2.8
	SD					4.4
	Median					-1.0
	Minimum					-11.3
	Maximum					0.3
Day 1: Post 2 hr	N	6	6	6	6	6
	Mean	60.7	64.5	58.2	62.5	58.4
	SD	4.3	13.2	13.1	6.7	10.2
	Median	62.0	65.0	57.5	59.5	57.7
	Minimum	54.0	50.0	38.0	57.0	41.7
	Maximum	65.0	82.0	73.0	75.0	73.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Change from Pre-dose	N	6	6	6	8
	Mean	0.9	-1.8	-1.5	-0.6
	SD	4.1	3.1	2.8	3.8
	Median	0.8	-1.0	-1.8	-0.3
	Minimum	-3.3	-5.7	-4.7	-8.3
	Maximum	7.0	2.0	3.3	3.7
Day 1: Post 2 hr	N	6	6	6	16
	Mean	61.8	53.7	55.1	57.7
	SD	7.0	10.5	7.4	7.0
	Median	62.3	51.5	53.7	55.3
	Minimum	54.0	43.7	47.3	49.0
	Maximum	72.3	74.0	64.3	70.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-4.2	2.8	-1.3	3.0	-2.7
	SD	5.3	8.7	3.8	5.5	4.5
	Median	-3.0	0.0	-1.5	5.5	-3.2
	Minimum	-14.0	-7.0	-7.0	-4.0	-9.7
	Maximum	1.0	17.0	4.0	8.0	2.3
Day 1: Post 3 hr	N	0	0	0	0	6
	Mean					61.3
	SD					10.1
	Median					63.8
	Minimum					44.7
	Maximum					73.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

ECG MEAN HEART RATE (beats/min) Statistics		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	0.2	-2.8	-4.2	-4.4
	SD	5.3	2.7	1.5	5.2
	Median	2.2	-1.8	-4.3	-4.0
	Minimum	-7.7	-7.7	-6.0	-14.0
	Maximum	5.0	-0.3	-2.0	4.0
Day 1: Post 3 hr	N	6	6	6	8
	Mean	66.7	57.9	67.2	61.8
	SD	8.0	11.3	4.6	6.2
	Median	65.0	53.3	66.5	61.7
	Minimum	59.0	49.3	63.3	54.3
	Maximum	81.7	79.7	75.7	69.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
		Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
ECG MEAN HEART RATE (beats/min)		(N = 6)	(N = 6)	(N = 6)	(N = 6)	(N = 6)
Change from Pre-dose	Statistics					
	N	0	0	0	0	6
	Mean					0.2
	SD					3.4
	Median					0.2
	Minimum					-3.3
	Maximum					6.0
Day 1: Post 4 hrs	N	6	6	6	6	6
	Mean	65.3	66.3	64.0	64.8	62.2
	SD	7.0	9.8	11.0	9.8	8.5
	Median	65.0	66.0	63.0	61.5	61.7
	Minimum	58.0	56.0	49.0	56.0	52.0
	Maximum	77.0	79.0	78.0	83.0	76.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Change from Pre-dose	N	6	6	6	8
	Mean	5.1	1.5	7.9	2.2
	SD	6.0	4.7	8.5	3.7
	Median	5.5	2.0	7.2	2.2
	Minimum	-3.3	-5.3	-1.7	-4.0
	Maximum	14.0	7.7	21.3	7.7
Day 1: Post 4 hrs	N	6	6	6	16
	Mean	71.7	59.6	65.4	64.1
	SD	8.0	11.6	4.1	6.6
	Median	70.8	56.5	66.7	63.0
	Minimum	58.3	49.3	59.3	53.0
	Maximum	82.0	82.3	69.7	76.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	0.5	4.7	4.5	5.3	1.1
	SD	9.9	6.9	3.4	4.8	4.6
	Median	2.0	4.5	3.5	5.0	-0.5
	Minimum	-12.0	-5.0	1.0	-1.0	-3.7
	Maximum	13.0	14.0	9.0	14.0	8.3
Day 1: Post 5 hrs	N	0	0	0	0	6
	Mean					59.3
	SD					6.7
	Median					58.8
	Minimum					51.0
	Maximum					68.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Change from Pre-dose	N	6	6	6	16
	Mean	10.1	3.1	6.1	2.0
	SD	2.4	4.3	5.1	6.0
	Median	10.0	4.5	5.0	3.0
	Minimum	7.0	-2.3	1.0	-11.0
	Maximum	14.3	7.3	14.3	9.7
Day 1: Post 5 hrs	N	6	6	6	8
	Mean	68.5	58.2	63.7	60.1
	SD	9.7	10.9	5.7	5.7
	Median	67.5	55.7	62.7	58.8
	Minimum	56.0	48.7	56.3	55.0
	Maximum	84.3	79.0	72.0	73.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	Statistics					
	N	0	0	0	0	6
	Mean					-1.8
	SD					5.0
	Median					-3.2
	Minimum					-7.0
	Maximum					7.3
Day 1: Post 6 hrs	N	6	6	6	6	6
	Mean	66.5	69.5	64.2	65.8	59.8
	SD	1.0	9.9	8.6	9.0	7.6
	Median	66.5	70.5	65.0	64.0	60.5
	Minimum	65.0	57.0	52.0	57.0	48.3
	Maximum	68.0	80.0	75.0	83.0	70.3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Change from Pre-dose	N	6	6	6	8
	Mean	6.9	1.8	4.4	0.5
	SD	7.2	2.7	2.8	7.2
	Median	6.8	2.0	3.3	2.8
	Minimum	-4.7	-2.7	2.0	-12.3
	Maximum	16.7	5.0	8.3	9.0
Day 1: Post 6 hrs	N	6	6	6	16
	Mean	69.6	60.0	64.5	64.8
	SD	7.4	9.7	6.1	8.0
	Median	68.0	59.5	64.7	63.3
	Minimum	62.7	48.3	58.3	50.7
	Maximum	82.7	77.7	75.0	84.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	1.7	7.8	4.7	6.3	-1.3
	SD	8.5	5.9	6.2	6.3	3.4
	Median	4.5	7.5	4.0	6.5	-2.0
	Minimum	-14.0	0.0	-4.0	-4.0	-4.7
	Maximum	10.0	14.0	12.0	15.0	4.7
Day 1: Post 8 hrs	N	0	0	0	0	6
	Mean					60.6
	SD					9.2
	Median					58.2
	Minimum					51.0
	Maximum					77.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

ECG MEAN HEART RATE (beats/min) Statistics		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	8.0	3.6	5.2	2.7
	SD	7.3	3.9	3.7	5.2
	Median	10.2	3.3	5.3	2.8
	Minimum	-4.7	-3.0	-0.7	-6.3
	Maximum	15.0	7.7	10.7	11.0
Day 1: Post 8 hrs	N	6	6	6	8
	Mean	66.1	59.8	64.1	62.6
	SD	5.1	10.8	3.4	5.7
	Median	66.0	57.5	64.0	61.3
	Minimum	59.3	47.3	60.3	55.7
	Maximum	73.7	79.7	69.3	73.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-0.4
	SD					7.0
	Median					-0.8
	Minimum					-9.0
	Maximum					7.3
Day 2: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Change from Pre-dose	N	6	6	6	8
	Mean	4.5	3.4	4.8	3.0
	SD	5.0	4.5	4.4	5.9
	Median	6.8	4.3	5.2	2.8
	Minimum	-4.3	-4.0	-2.7	-4.3
	Maximum	8.0	8.7	9.3	14.0
Day 2: Pre-dose	N	6	6	6	6
	Mean	64.1	56.0	59.8	58.3
	SD	9.3	10.9	4.2	6.1
	Median	63.5	53.0	59.3	58.2
	Minimum	50.7	47.7	54.3	51.0
	Maximum	78.0	77.7	65.3	68.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	Statistics					
	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 2: Post 24 hrs	N	6	6	6	6	6
	Mean	67.7	67.5	57.7	64.0	57.0
	SD	10.8	9.6	12.7	9.8	8.1
	Median	71.0	70.0	56.0	64.0	56.8
	Minimum	53.0	55.0	38.0	53.0	44.3
	Maximum	78.0	79.0	73.0	79.0	69.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics					
Change from Day 1: Pre-dose	N	6	6	6	6
	Mean	2.4	-0.4	0.6	0.1
	SD	6.5	2.5	3.5	4.9
	Median	1.8	0.0	0.7	1.3
	Minimum	-5.3	-3.7	-4.7	-9.7
	Maximum	10.3	2.7	5.3	4.0
Day 2: Post 24 hrs	N	0	0	0	10
	Mean				60.6
	SD				6.9
	Median				59.0
	Minimum				52.0
	Maximum				71.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
ECG MEAN HEART RATE (beats/min)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	6	6	6	6	6
	Mean	2.8	5.8	-1.8	4.5	-4.1
	SD	11.4	6.7	4.4	6.3	4.0
	Median	5.5	4.0	-1.5	1.5	-4.3
	Minimum	-15.0	-1.0	-8.0	-1.0	-8.3
	Maximum	13.0	18.0	4.0	14.0	0.7
Day 3: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

ECG MEAN HEART RATE (beats/min) Statistics		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	0	0	0	10
	Mean				-3.7
	SD				6.7
	Median				-4.5
	Minimum				-15.0
	Maximum				7.0
Day 3: Pre-dose	N	6	5	6	6
	Mean	67.7	57.5	63.4	60.3
	SD	7.0	5.0	6.8	7.6
	Median	65.5	55.3	62.7	60.3
	Minimum	61.7	53.3	56.3	53.0
	Maximum	81.3	64.3	75.7	74.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
			Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
ECG MEAN HEART RATE (beats/min)			(N = 6)	(N = 6)	(N = 6)	(N = 6)	(N = 6)
5.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 4: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
ECG MEAN HEART RATE (beats/min)			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics						
5.15	N		6	5	6	6
	Mean		6.1	4.7	4.1	2.2
	SD		6.6	2.9	10.0	5.6
	Median		5.8	3.7	0.3	3.8
	Minimum		-3.0	2.0	-5.7	-8.7
	Maximum		13.7	8.3	21.3	7.0
Day 4: Pre-dose	N		6	3	5	6
	Mean		68.3	55.9	61.9	60.3
	SD		8.6	5.5	2.5	8.2
	Median		69.3	54.3	61.3	58.0
	Minimum		56.0	51.3	59.3	52.7
	Maximum		78.0	62.0	66.0	75.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
			Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
			(N = 6)	(N = 6)	(N = 6)	(N = 6)	(N = 6)
ECG MEAN HEART RATE (beats/min)	Statistics						
6.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 5: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
ECG MEAN HEART RATE (beats/min)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
6.15	N	6	3	5	6
	Mean	6.7	4.2	1.2	2.1
	SD	4.9	4.7	7.6	5.9
	Median	5.7	3.3	0.7	4.2
	Minimum	0.3	0.0	-7.3	-7.0
	Maximum	14.0	9.3	11.7	8.7
Day 5: Pre-dose	N	6	3	5	6
	Mean	67.2	55.7	62.5	65.5
	SD	11.4	4.7	3.9	9.3
	Median	64.2	57.7	60.3	64.5
	Minimum	53.7	50.3	59.0	52.3
	Maximum	86.3	59.0	67.7	79.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
			Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
			(N = 6)	(N = 6)	(N = 6)	(N = 6)	(N = 6)
ECG MEAN HEART RATE (beats/min)	Statistics						
7.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 6: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
ECG MEAN HEART RATE (beats/min)			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
7.15	N		6	3	5	6
	Mean		5.6	4.0	1.8	7.3
	SD		6.7	4.3	8.0	8.5
	Median		2.8	6.3	-0.3	10.2
	Minimum		0.7	-1.0	-8.3	-7.7
	Maximum		18.7	6.7	13.3	15.3
Day 6: Pre-dose	N		6	0	5	4
	Mean		68.3		64.4	59.3
	SD		8.2		3.6	6.8
	Median		67.8		63.7	60.7
	Minimum		57.3		60.7	50.0
	Maximum		82.0		70.3	66.0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
			Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
ECG MEAN HEART RATE (beats/min)			(N = 6)	(N = 6)	(N = 6)	(N = 6)	(N = 6)
8.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 7: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
ECG MEAN HEART RATE (beats/min)			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Statistics						
8.15	N		6	0	5	4
	Mean		6.7		3.7	1.3
	SD		5.3		8.4	8.0
	Median		7.0		3.3	2.0
	Minimum		-0.3		-5.7	-9.0
	Maximum		14.3		16.0	10.3
Day 7: Pre-dose	N		6	0	5	4
	Mean		67.1		62.9	58.4
	SD		9.7		3.0	5.0
	Median		65.5		61.3	57.7
	Minimum		55.3		60.3	53.7
	Maximum		83.0		66.7	64.7

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
			Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
			(N = 6)	(N = 6)	(N = 6)	(N = 6)	(N = 6)
ECG MEAN HEART RATE (beats/min)	Statistics						
9.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 8: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
ECG MEAN HEART RATE (beats/min)			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
9.15	N		6	0	5	4
	Mean		5.4		2.2	0.4
	SD		5.5		7.4	7.9
	Median		4.5		1.0	0.7
	Minimum		-1.3		-8.3	-8.7
	Maximum		15.3		11.3	9.0
Day 8: Pre-dose	N		6	0	5	4
	Mean		64.9		63.1	60.9
	SD		7.4		3.6	3.8
	Median		65.5		63.7	59.7
	Minimum		54.7		58.3	58.0
	Maximum		75.3		67.0	66.3

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	143.0	165.3	164.8	138.3	158.9
	SD	13.3	16.1	5.8	14.8	9.5
	Median	145.5	159.5	165.0	140.5	157.5
	Minimum	118	150	158	121	149
	Maximum	155	186	172	157	174
Day 0	N	6	6	6	6	6
	Mean	148.0	170.2	168.5	141.7	160.5
	SD	12.0	14.4	14.6	13.1	11.2
	Median	145.5	167.0	171.0	142.0	161.8
	Minimum	136	154	143	120	146
	Maximum	164	192	184	155	173

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	172.1	153.1	169.6	160.5
	SD	22.6	13.6	15.2	15.8
	Median	178.2	151.7	175.5	164.7
	Minimum	135	135	144	132
	Maximum	198	177	183	190
Day 0	N	6	6	6	16
	Mean	174.3	155.3	165.0	160.1
	SD	21.5	20.7	13.3	15.9
	Median	176.0	151.3	169.3	166.5
	Minimum	140	128	144	126
	Maximum	199	191	182	185

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Pre-dose	N	6	6	6	6	6
	Mean	145.7	167.0	168.5	141.5	163.7
	SD	14.0	19.5	14.8	14.2	9.3
	Median	146.0	165.5	163.5	143.5	166.0
	Minimum	123	140	153	121	151
	Maximum	160	189	191	158	177
Day 1: Post 1 hr	N	0	0	0	0	6
	Mean					162.1
	SD					9.6
	Median					161.5
	Minimum					149
	Maximum					174

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1: Pre-dose	N	6	6	6	16
	Mean	172.4	155.7	171.3	165.6
	SD	20.7	15.7	17.7	20.1
	Median	173.2	152.7	176.2	168.5
	Minimum	142	136	148	133
	Maximum	195	181	191	193
Day 1: Post 1 hr	N	6	6	6	8
	Mean	171.2	153.1	169.3	162.3
	SD	22.0	12.6	15.6	21.4
	Median	176.0	151.0	173.0	163.3
	Minimum	134	141	147	135
	Maximum	192	172	188	194

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-1.6
	SD					10.8
	Median					0.83
	Minimum					-21
	Maximum					9
Day 1: Post 2 hr	N	6	6	6	6	6
	Mean	148.8	159.5	171.8	144.5	162.1
	SD	8.7	19.6	22.1	14.1	10.2
	Median	150.5	156.5	170.0	147.5	163.5
	Minimum	133	131	139	127	148
	Maximum	156	185	203	159	175

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-1.2	-2.6	-1.9	3.0
	SD	6.9	6.5	3.4	6.6
	Median	-2.83	-2.67	-2.00	0.50
	Minimum	-8	-11	-6	-5
	Maximum	11	5	4	15
Day 1: Post 2 hr	N	6	6	6	16
	Mean	172.4	154.1	168.4	164.3
	SD	24.3	12.1	17.0	17.4
	Median	177.3	154.8	170.8	166.0
	Minimum	130	135	144	135
	Maximum	197	172	188	195

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	3.2	-7.5	3.3	3.0	-1.6
	SD	6.1	5.7	9.0	5.4	11.8
	Median	4.00	-9.00	5.50	4.50	1.67
	Minimum	-4	-14	-14	-4	-24
	Maximum	10	2	12	9	8
Day 1: Post 3 hr	N	0	0	0	0	6
	Mean					162.7
	SD					11.0
	Median					163.3
	Minimum					145
	Maximum					176

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	0.1	-1.6	-2.8	-1.3
	SD	12.1	4.9	4.8	7.7
	Median	-1.50	0.67	-4.67	-0.17
	Minimum	-12	-9	-8	-21
	Maximum	20	2	4	10
Day 1: Post 3 hr	N	6	6	6	8
	Mean	170.8	153.9	168.9	159.5
	SD	23.7	15.5	15.2	19.0
	Median	172.8	154.5	167.3	154.2
	Minimum	132	133	145	138
	Maximum	197	176	187	185

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-1.0
	SD					10.6
	Median					2.67
	Minimum					-20
	Maximum					9
Day 1: Post 4 hrs	N	6	6	6	6	6
	Mean	148.7	164.8	171.5	142.8	163.6
	SD	8.4	22.3	9.9	13.9	11.7
	Median	149.5	158.5	171.0	145.5	164.3
	Minimum	139	137	158	120	145
	Maximum	159	196	186	157	181

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-1.6	-1.7	-2.3	0.2
	SD	7.8	6.6	7.6	6.4
	Median	-0.83	-2.00	-3.50	-0.50
	Minimum	-11	-12	-9	-11
	Maximum	9	8	12	9
Day 1: Post 4 hrs	N	6	6	6	16
	Mean	170.0	152.0	166.6	164.4
	SD	17.8	16.6	14.8	19.5
	Median	167.3	149.5	169.0	163.5
	Minimum	143	126	141	136
	Maximum	192	175	181	201

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	3.0	-2.2	3.0	1.3	-0.1
	SD	8.2	5.2	6.1	3.6	9.5
	Median	1.00	-2.50	5.00	2.00	-1.50
	Minimum	-5	-7	-5	-4	-12
	Maximum	16	7	10	5	14
Day 1: Post 5 hrs	N	0	0	0	0	6
	Mean					162.5
	SD					10.5
	Median					162.2
	Minimum					148
	Maximum					179

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-2.4	-3.7	-4.7	-1.2
	SD	6.3	4.1	6.6	8.2
	Median	-0.50	-3.50	-5.50	-0.50
	Minimum	-12	-10	-11	-27
	Maximum	6	2	7	8
Day 1: Post 5 hrs	N	6	6	6	8
	Mean	166.9	150.8	166.2	157.3
	SD	18.0	17.2	14.8	16.8
	Median	169.7	149.3	167.7	155.8
	Minimum	135	127	145	137
	Maximum	186	177	184	181

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-1.2
	SD					7.9
	Median					-2.00
	Minimum					-10
	Maximum					12
Day 1: Post 6 hrs	N	6	6	6	6	6
	Mean	143.5	161.7	169.0	144.2	161.4
	SD	5.4	16.9	10.9	14.5	9.3
	Median	144.5	156.5	167.5	143.0	163.7
	Minimum	134	144	157	124	147
	Maximum	150	184	183	165	172

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-5.5	-4.9	-5.1	-2.0
	SD	8.0	2.5	10.7	7.1
	Median	-7.17	-4.83	-2.00	-1.33
	Minimum	-15	-9	-20	-14
	Maximum	4	-2	8	9
Day 1: Post 6 hrs	N	6	6	6	16
	Mean	167.0	151.2	165.1	160.7
	SD	21.9	18.5	12.5	19.7
	Median	170.0	150.5	165.5	160.2
	Minimum	131	123	151	122
	Maximum	192	179	178	189

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-2.2	-5.3	0.5	2.7	-2.3
	SD	9.9	10.5	6.9	9.0	5.4
	Median	-2.00	-6.50	2.50	3.50	-2.33
	Minimum	-16	-20	-11	-13	-9
	Maximum	11	8	7	15	5
Day 1: Post 8 hrs	N	0	0	0	0	6
	Mean					160.7
	SD					10.6
	Median					163.3
	Minimum					142
	Maximum					171

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-5.4	-4.5	-6.2	-4.9
	SD	11.9	4.4	11.0	4.7
	Median	-6.33	-2.50	-4.50	-4.50
	Minimum	-23	-13	-23	-13
	Maximum	8	-2	6	3
Day 1: Post 8 hrs	N	6	6	6	8
	Mean	165.4	150.8	162.1	159.0
	SD	21.1	17.9	13.1	17.9
	Median	170.8	149.0	167.0	160.8
	Minimum	130	125	144	134
	Maximum	182	178	173	184

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-3.0
	SD					7.6
	Median					-3.00
	Minimum					-11
	Maximum					5
Day 2: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-7.0	-4.8	-9.2	-0.3
	SD	11.8	5.6	7.3	11.2
	Median	-11.8	-4.83	-7.84	-2.17
	Minimum	-19	-11	-21	-15
	Maximum	14	4	-2	19
Day 2: Pre-dose	N	6	6	6	6
	Mean	171.5	156.2	170.8	159.7
	SD	19.8	18.2	17.0	19.5
	Median	174.5	152.7	174.8	155.8
	Minimum	137	138	150	139
	Maximum	192	189	192	186

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 2: Post 24 hrs	N	6	6	6	6	6
	Mean	146.7	171.8	170.5	142.5	160.1
	SD	16.2	13.8	18.2	17.2	12.6
	Median	153.0	172.5	175.0	145.0	156.2
	Minimum	117	154	141	119	147
	Maximum	161	194	192	161	177

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	6	6	6	6
	Mean	-0.9	0.5	-0.4	5.0
	SD	5.6	4.2	4.9	9.4
	Median	-3.17	-0.00	0.17	3.17
	Minimum	-6	-3	-7	-5
	Maximum	7	8	6	22
Day 2: Post 24 hrs	N	0	0	0	10
	Mean				172.0
	SD				16.5
	Median				172.5
	Minimum				148
	Maximum				199

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	6	6	6	6	6
	Mean	1.0	4.8	2.0	1.0	-3.6
	SD	9.3	10.8	10.8	5.3	8.9
	Median	-1.50	4.50	0.50	0.50	-5.33
	Minimum	-8	-12	-12	-5	-14
	Maximum	17	21	16	9	12
Day 3: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	0	0	0	10
	Mean				-0.2
	SD				4.3
	Median				0.33
	Minimum				-8
	Maximum				6
Day 3: Pre-dose	N	6	5	6	6
	Mean	168.0	161.7	170.6	160.8
	SD	17.0	16.9	16.8	19.8
	Median	171.8	156.0	175.3	160.0
	Minimum	136	147	147	136
	Maximum	185	189	187	185

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4: Pre-dose	5.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
5.15	N	6	5	6	6
	Mean	-4.4	2.1	-0.7	6.2
	SD	8.5	4.0	2.1	11.5
	Median	-4.50	1.67	-0.50	5.00
	Minimum	-16	-3	-4	-10
	Maximum	8	8	2	24
Day 4: Pre-dose	N	6	3	5	6
	Mean	176.7	154.7	169.2	155.9
	SD	20.5	12.2	17.8	22.3
	Median	182.7	155.7	176.7	149.2
	Minimum	139	142	145	134
	Maximum	196	166	186	188

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 5: Pre-dose	6.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
6.15	N	6	3	5	6
	Mean	4.3	-0.1	-1.3	1.2
	SD	14.1	3.8	4.7	6.5
	Median	-0.17	1.00	-0.33	1.67
	Minimum	-11	-4	-9	-9
	Maximum	28	3	4	10
Day 5: Pre-dose	N	6	3	5	6
	Mean	172.6	155.2	170.9	157.8
	SD	19.8	9.1	18.1	18.3
	Median	180.0	152.7	175.3	152.3
	Minimum	137	148	151	140
	Maximum	192	165	188	186

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
7.15	N	0	0	0	0	0	
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 6: Pre-dose	N	0	0	0	0	0	
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
7.15	N	6	3	5	6
	Mean	0.2	0.4	0.4	3.1
	SD	10.1	0.8	3.4	7.8
	Median	0.00	0.00	1.33	3.33
	Minimum	-15	0	-4	-7
	Maximum	15	1	4	14
Day 6: Pre-dose	N	6	0	5	4
	Mean	169.9		171.7	157.4
	SD	20.3		17.7	19.5
	Median	172.2		170.0	153.5
	Minimum	135		152	141
	Maximum	195		194	182

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 7: Pre-dose	8.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
8.15	N	6	0	5	4
	Mean	-2.4		1.3	5.3
	SD	7.2		5.2	6.9
	Median	-2.50		3.00	5.67
	Minimum	-12		-7	-3
	Maximum	6		6	13
Day 7: Pre-dose	N	6	0	5	4
	Mean	175.5		171.7	152.6
	SD	19.9		17.9	23.1
	Median	180.7		167.7	149.8
	Minimum	143		152	128
	Maximum	193		196	183

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
9.15	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 8: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

PR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
9.15	N	6	0	5	4
	Mean	3.1		1.3	0.4
	SD	10.2		6.9	4.6
	Median	0.17		4.00	1.17
	Minimum	-7		-9	-5
	Maximum	22		8	5
Day 8: Pre-dose	N	6	0	5	4
	Mean	168.7		172.3	155.9
	SD	16.6		16.6	20.6
	Median	173.5		169.0	151.2
	Minimum	141		154	138
	Maximum	190		193	184

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	90.0	90.5	94.2	98.0	92.0
	SD	7.2	8.3	14.1	7.2	6.9
	Median	89.5	91.0	91.5	97.0	92.2
	Minimum	82	81	77	89	81
	Maximum	103	103	115	109	101
Day 0	N	6	6	6	6	6
	Mean	89.2	91.3	91.2	100.2	93.3
	SD	3.3	8.9	17.3	9.6	5.1
	Median	89.0	88.5	89.5	99.0	94.8
	Minimum	85	83	70	90	87
	Maximum	93	106	114	111	99

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	96.4	88.2	90.6	95.9
	SD	11.6	8.5	6.1	9.7
	Median	91.0	85.0	92.8	93.0
	Minimum	86	81	81	77
	Maximum	115	104	96	117
Day 0	N	6	6	6	16
	Mean	92.6	92.3	90.8	96.7
	SD	10.4	3.2	7.5	10.6
	Median	90.3	91.8	93.2	97.2
	Minimum	82	88	80	76
	Maximum	112	96	99	115

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Pre-dose	N	6	6	6	6	6
	Mean	88.8	91.7	95.3	98.2	93.7
	SD	4.4	9.4	14.6	9.6	5.4
	Median	88.5	89.5	93.0	94.5	94.7
	Minimum	83	81	77	89	87
	Maximum	95	103	117	113	99
Day 1: Post 1 hr	N	0	0	0	0	6
	Mean					94.0
	SD					5.3
	Median					94.2
	Minimum					87
	Maximum					101

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1: Pre-dose	N	6	6	6	16
	Mean	94.2	89.6	90.8	96.5
	SD	7.8	3.9	5.3	10.2
	Median	90.5	89.8	93.5	100.5
	Minimum	88	84	81	78
	Maximum	108	95	94	112
Day 1: Post 1 hr	N	6	6	6	8
	Mean	93.9	92.7	91.8	99.7
	SD	9.0	2.0	6.9	9.3
	Median	91.8	91.8	93.8	104.0
	Minimum	87	92	79	80
	Maximum	111	97	99	106

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					0.3
	SD					3.1
	Median					1.0
	Minimum					-6
	Maximum					3
Day 1: Post 2 hr	N	6	6	6	6	6
	Mean	91.0	91.5	99.0	99.5	93.6
	SD	7.1	9.0	10.7	10.7	5.1
	Median	89.5	89.5	94.0	97.0	94.3
	Minimum	85	83	90	89	87
	Maximum	105	105	117	113	99

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Protocol: LB-102-001

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-0.3	3.1	1.0	-0.2
	SD	3.3	3.1	2.3	2.0
	Median	-0.2	2.7	0.5	0.2
	Minimum	-5	-1	-2	-4
	Maximum	3	8	5	2
Day 1: Post 2 hr	N	6	6	6	16
	Mean	94.3	92.6	90.6	95.2
	SD	9.3	3.8	7.5	9.9
	Median	90.5	91.5	93.7	96.7
	Minimum	87	89	76	77
	Maximum	111	99	96	106

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	2.2	-0.2	3.7	1.3	-0.1
	SD	8.0	2.8	6.3	4.8	2.1
	Median	1.0	0.0	1.0	2.0	0.0
	Minimum	-8	-5	-2	-7	-3
	Maximum	15	3	15	6	2
Day 1: Post 3 hr	N	0	0	0	0	6
	Mean					95.8
	SD					5.5
	Median					95.8
	Minimum					89
	Maximum					103

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	0.1	2.9	-0.2	-1.4
	SD	1.7	4.2	2.5	4.8
	Median	-0.2	4.2	0.3	-0.3
	Minimum	-2	-2	-4	-11
	Maximum	3	7	2	8
Day 1: Post 3 hr	N	6	6	6	8
	Mean	97.3	94.0	91.7	101.5
	SD	11.1	4.3	9.5	10.2
	Median	92.3	95.5	94.7	105.0
	Minimum	88	86	75	83
	Maximum	115	98	102	110

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					2.2
	SD					3.3
	Median					2.5
	Minimum					-4
	Maximum					6
Day 1: Post 4 hrs	N	6	6	6	6	6
	Mean	92.8	92.3	98.2	97.7	93.8
	SD	5.9	11.1	13.2	9.3	5.6
	Median	91.0	89.0	94.0	93.0	93.5
	Minimum	87	82	85	90	86
	Maximum	103	106	119	111	102

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	3.1	4.4	0.9	1.6
	SD	3.6	2.8	4.8	4.3
	Median	2.0	4.3	0.7	2.0
	Minimum	-1	1	-5	-8
	Maximum	8	8	8	6
Day 1: Post 4 hrs	N	6	6	6	16
	Mean	94.5	91.8	90.4	95.3
	SD	10.2	3.7	7.2	9.7
	Median	91.3	90.8	93.3	97.7
	Minimum	83	88	78	78
	Maximum	111	97	96	107

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	4.0	0.7	2.8	-0.5	0.2
	SD	5.5	2.8	4.3	2.4	1.9
	Median	3.0	1.0	2.0	-0.5	-0.5
	Minimum	-3	-3	-4	-3	-2
	Maximum	13	4	8	2	3
Day 1: Post 5 hrs	N	0	0	0	0	6
	Mean					92.6
	SD					5.3
	Median					91.7
	Minimum					86
	Maximum					99

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	0.3	2.2	-0.3	-1.3
	SD	2.9	5.1	2.3	4.5
	Median	0.8	3.7	-0.2	-0.5
	Minimum	-4	-7	-3	-14
	Maximum	3	7	2	4
Day 1: Post 5 hrs	N	6	6	6	8
	Mean	95.2	89.4	89.9	98.5
	SD	9.7	1.9	6.8	9.0
	Median	90.3	89.0	92.5	101.7
	Minimum	88	88	77	78
	Maximum	111	93	95	107

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-1.1
	SD					1.8
	Median					-1.0
	Minimum					-3
	Maximum					2
Day 1: Post 6 hrs	N	6	6	6	6	6
	Mean	90.8	91.3	94.5	98.0	94.2
	SD	3.2	12.8	14.2	8.5	5.2
	Median	90.0	89.5	91.5	96.0	94.2
	Minimum	87	75	78	89	86
	Maximum	96	110	116	109	101

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	1.0	-0.2	-0.8	-1.3
	SD	2.5	3.7	1.6	2.9
	Median	0.7	-0.2	-0.7	-1.2
	Minimum	-2	-6	-4	-6
	Maximum	5	6	1	4
Day 1: Post 6 hrs	N	6	6	6	16
	Mean	93.1	90.1	90.6	97.6
	SD	10.3	3.7	7.1	9.3
	Median	88.5	90.3	92.8	101.2
	Minimum	84	84	77	80
	Maximum	110	95	98	107

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	2.0	-0.3	-0.8	-0.2	0.5
	SD	4.2	5.8	3.1	5.9	2.1
	Median	3.5	-0.5	-0.5	0.0	-0.5
	Minimum	-6	-10	-6	-7	-1
	Maximum	6	7	3	8	4
Day 1: Post 8 hrs	N	0	0	0	0	6
	Mean					91.3
	SD					4.7
	Median					92.3
	Minimum					83
	Maximum					97

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-1.2	0.5	-0.2	1.1
	SD	2.6	1.2	2.4	4.2
	Median	-1.8	0.7	-0.5	1.3
	Minimum	-4	-2	-3	-8
	Maximum	2	2	4	7
Day 1: Post 8 hrs	N	6	6	6	8
	Mean	92.7	88.4	87.3	96.9
	SD	10.0	5.1	7.4	8.6
	Median	88.3	88.3	89.7	99.8
	Minimum	85	80	74	79
	Maximum	109	94	94	105

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-2.3
	SD					2.5
	Median					-2.5
	Minimum					-5
	Maximum					2
Day 2: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-1.5	-1.2	-3.5	-2.9
	SD	2.6	2.1	3.0	2.5
	Median	-1.7	-1.5	-3.7	-3.0
	Minimum	-5	-3	-7	-6
	Maximum	1	3	1	1
Day 2: Pre-dose	N	6	6	6	6
	Mean	93.0	90.6	91.7	98.8
	SD	8.9	4.3	3.2	9.6
	Median	90.7	90.8	92.0	102.3
	Minimum	85	85	88	80
	Maximum	110	96	96	108

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 2: Post 24 hrs	N	6	6	6	6	6
	Mean	87.2	88.8	96.7	97.0	95.3
	SD	3.0	8.3	16.4	10.0	4.1
	Median	87.0	88.0	95.0	91.5	96.0
	Minimum	83	81	72	90	90
	Maximum	91	104	118	113	101

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	6	6	6	6
	Mean	-1.2	1.0	0.9	0.7
	SD	3.1	1.6	3.4	2.1
	Median	-1.3	1.2	0.2	1.2
	Minimum	-6	-1	-2	-2
	Maximum	2	3	7	3
Day 2: Post 24 hrs	N	0	0	0	10
	Mean				94.6
	SD				9.6
	Median				93.0
	Minimum				82
	Maximum				111

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	6	6	6	6	6
	Mean	-1.7	-2.8	1.3	-1.2	1.7
	SD	1.6	6.8	6.5	4.6	4.4
	Median	-1.5	-3.5	-0.5	-2.0	2.2
	Minimum	-4	-14	-5	-7	-3
	Maximum	0	6	13	6	9
Day 3: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	0	0	0	10
	Mean				-1.0
	SD				4.3
	Median				-0.5
	Minimum				-11
	Maximum				4
Day 3: Pre-dose	N	6	5	6	6
	Mean	94.4	92.7	90.7	96.9
	SD	8.3	1.8	6.4	9.0
	Median	91.0	92.0	91.8	101.3
	Minimum	88	91	80	81
	Maximum	109	96	98	103

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4: Pre-dose	5.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
QRS DURATION, AGGREGATE (msec)	Statistics					
	5.15	N	6	5	6	6
		Mean	0.2	1.9	-0.1	-1.2
		SD	6.1	3.6	3.0	2.1
		Median	-1.5	3.0	-0.7	-1.7
		Minimum	-7	-4	-3	-4
		Maximum	12	5	5	2
Day 4: Pre-dose		N	6	3	5	6
		Mean	90.1	92.2	90.0	98.0
		SD	10.0	2.5	8.8	10.6
		Median	88.5	93.7	91.3	102.5
		Minimum	81	89	80	79
		Maximum	109	94	102	107

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 5: Pre-dose	6.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
QRS DURATION, AGGREGATE (msec)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
6.15	N	6	3	5	6
	Mean	-4.1	1.6	-0.2	-0.1
	SD	7.1	1.3	5.5	1.6
	Median	-1.3	1.3	-0.7	0.0
	Minimum	-18	0	-6	-3
	Maximum	1	3	8	2
Day 5: Pre-dose	N	6	3	5	6
	Mean	91.7	92.8	90.1	97.6
	SD	9.3	5.4	6.9	10.2
	Median	88.2	90.0	91.7	101.0
	Minimum	87	89	79	79
	Maximum	111	99	97	107

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 6: Pre-dose	7.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
QRS DURATION, AGGREGATE (msec)					
	7.15				
	N	6	3	5	6
	Mean	-2.6	2.1	-0.1	-0.5
	SD	4.6	5.5	2.7	2.2
	Median	-1.8	0.3	-1.0	-0.5
	Minimum	-11	-2	-3	-3
	Maximum	3	8	4	3
Day 6: Pre-dose					
	N	6	0	5	4
	Mean	90.8		90.7	99.8
	SD	9.6		6.0	7.5
	Median	88.5		92.3	102.5
	Minimum	81		84	89
	Maximum	109		98	105

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 7: Pre-dose	8.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
QRS DURATION, AGGREGATE (msec)	Statistics					
	8.15	N	6	0	5	4
		Mean	-3.4		0.5	-1.6
		SD	7.0		4.0	3.9
		Median	-1.2		0.3	-0.5
		Minimum	-18		-5	-7
		Maximum	1		5	2
Day 7: Pre-dose		N	6	0	5	4
		Mean	92.3		88.7	100.4
		SD	8.7		8.5	7.0
		Median	89.0		91.7	101.5
		Minimum	85		80	91
		Maximum	109		99	108

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8: Pre-dose	9.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QRS DURATION, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
9.15	N	6	0	5	4
	Mean	-1.9		-1.5	-0.9
	SD	2.4		4.8	3.3
	Median	-2.2		-1.3	-1.2
	Minimum	-6		-9	-5
	Maximum	1		5	3
Day 8: Pre-dose	N	6	0	5	4
	Mean	92.1		89.4	101.8
	SD	9.2		7.4	7.3
	Median	90.0		92.0	102.8
	Minimum	83		81	92
	Maximum	110		97	109

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	414.8	393.8	402.3	391.8	389.9
	SD	26.2	17.5	35.8	27.7	25.7
	Median	408.5	395.5	389.5	390.5	387.5
	Minimum	379	370	372	359	362
	Maximum	451	421	467	427	431
Day 0	N	6	6	6	6	6
	Mean	409.7	376.5	397.5	396.5	385.9
	SD	16.5	26.0	46.6	23.9	26.8
	Median	417.0	374.5	380.5	394.5	380.0
	Minimum	386	347	365	369	355
	Maximum	426	419	489	428	418

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	381.4	380.3	403.5	398.7
	SD	11.5	25.4	6.6	19.5
	Median	381.3	387.3	405.2	397.8
	Minimum	367	348	394	366
	Maximum	398	410	410	437
Day 0	N	6	6	6	16
	Mean	371.7	391.7	405.1	402.4
	SD	16.8	30.1	24.7	19.3
	Median	374.2	398.8	401.8	402.5
	Minimum	347	351	376	356
	Maximum	391	421	441	435

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Pre-dose	N	6	6	6	6	6
	Mean	402.8	386.3	405.0	401.8	389.6
	SD	18.1	25.9	42.3	25.7	31.2
	Median	410.0	379.0	388.5	410.0	384.5
	Minimum	373	361	372	366	355
	Maximum	418	436	481	432	427
Day 1: Post 1 hr	N	0	0	0	0	6
	Mean					411.3
	SD					21.1
	Median					406.3
	Minimum					390
	Maximum					445

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1: Pre-dose	N	6	6	6	16
	Mean	392.8	408.7	395.2	396.3
	SD	23.8	25.9	25.2	19.7
	Median	392.8	417.2	400.2	390.7
	Minimum	361	369	364	367
	Maximum	431	432	434	446
Day 1: Post 1 hr	N	6	6	6	8
	Mean	387.4	422.6	411.3	397.0
	SD	18.0	28.1	23.3	24.2
	Median	387.0	436.7	418.8	399.8
	Minimum	360	375	381	358
	Maximum	411	444	439	435

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					21.8
	SD					16.3
	Median					18.7
	Minimum					2
	Maximum					46
Day 1: Post 2 hr	N	6	6	6	6	6
	Mean	413.7	389.8	424.7	425.8	418.6
	SD	17.2	24.4	42.8	20.2	24.3
	Median	421.5	385.0	406.5	421.0	423.5
	Minimum	383	366	394	405	382
	Maximum	428	434	507	458	450

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-5.4	13.9	16.1	-2.5
	SD	12.9	8.9	7.0	6.0
	Median	-2.8	11.3	17.0	-1.8
	Minimum	-20	6	5	-11
	Maximum	14	31	26	5
Day 1: Post 2 hr	N	6	6	6	16
	Mean	394.8	427.6	420.7	399.4
	SD	21.2	31.1	24.2	18.5
	Median	398.0	433.2	424.5	399.5
	Minimum	359	375	390	366
	Maximum	422	464	456	434

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	10.8	3.5	19.7	24.0	29.0
	SD	6.0	10.6	9.8	15.2	16.3
	Median	8.5	1.0	22.5	24.5	25.7
	Minimum	6	-9	6	6	7
	Maximum	21	17	30	49	55
Day 1: Post 3 hr	N	0	0	0	0	6
	Mean					418.1
	SD					27.4
	Median					417.3
	Minimum					379
	Maximum					461

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	2.0	18.9	25.5	3.0
	SD	11.4	14.6	4.2	9.9
	Median	0.2	16.0	26.5	4.2
	Minimum	-11	6	19	-16
	Maximum	17	38	32	18
Day 1: Post 3 hr	N	6	6	6	8
	Mean	385.3	413.6	399.2	392.9
	SD	18.4	45.0	16.1	19.6
	Median	383.5	430.7	400.0	396.8
	Minimum	359	323	379	361
	Maximum	409	443	425	424

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					28.6
	SD					16.0
	Median					30.5
	Minimum					5
	Maximum					50
Day 1: Post 4 hrs	N	6	6	6	6	6
	Mean	398.7	381.5	402.5	411.7	408.9
	SD	30.6	20.2	32.6	23.1	25.3
	Median	408.5	382.5	389.0	409.0	415.7
	Minimum	342	353	376	388	370
	Maximum	426	409	456	440	441

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-7.5	4.9	3.9	-6.5
	SD	12.1	28.1	19.4	10.6
	Median	-1.8	11.0	9.7	-4.2
	Minimum	-24	-46	-31	-22
	Maximum	4	34	23	10
Day 1: Post 4 hrs	N	6	6	6	16
	Mean	375.7	408.1	388.4	388.4
	SD	19.5	22.9	17.6	16.9
	Median	370.7	411.5	385.3	389.5
	Minimum	352	366	367	354
	Maximum	409	431	417	414

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-4.2	-4.8	-2.5	9.8	19.3
	SD	17.4	17.4	11.2	15.1	15.0
	Median	0.5	-1.5	1.0	16.0	19.0
	Minimum	-31	-27	-25	-12	-5
	Maximum	19	15	6	23	41
Day 1: Post 5 hrs	N	0	0	0	0	6
	Mean					407.6
	SD					29.0
	Median					409.5
	Minimum					372
	Maximum					454

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-17.1	-0.6	-6.8	-7.9
	SD	8.4	14.0	13.4	12.9
	Median	-16.2	-0.5	-8.0	-7.5
	Minimum	-31	-24	-23	-32
	Maximum	-9	19	12	19
Day 1: Post 5 hrs	N	6	6	6	8
	Mean	377.1	402.2	386.8	390.5
	SD	20.6	27.5	19.5	19.2
	Median	372.2	408.2	384.7	392.2
	Minimum	349	359	362	353
	Maximum	407	437	418	420

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas



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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					18.1
	SD					14.3
	Median					18.7
	Minimum					-8
	Maximum					33
Day 1: Post 6 hrs	N	6	6	6	6	6
	Mean	396.0	374.5	397.8	406.2	408.9
	SD	16.6	17.0	29.5	24.2	26.2
	Median	401.0	378.5	389.5	406.0	413.3
	Minimum	365	352	373	380	372
	Maximum	408	393	451	440	441

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-15.7	-6.4	-8.4	-8.9
	SD	8.0	8.0	9.3	14.5
	Median	-13.0	-6.7	-8.3	-8.2
	Minimum	-27	-17	-21	-29
	Maximum	-7	4	5	9
Day 1: Post 6 hrs	N	6	6	6	16
	Mean	373.7	401.3	388.2	389.4
	SD	21.2	23.4	19.1	19.9
	Median	367.2	409.8	393.0	387.7
	Minimum	348	367	364	351
	Maximum	401	428	408	439

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-6.8	-11.8	-7.2	4.3	19.3
	SD	9.0	20.4	13.8	14.4	11.6
	Median	-6.5	-10.0	-1.0	4.0	18.3
	Minimum	-22	-43	-30	-12	2
	Maximum	4	11	5	23	38
Day 1: Post 8 hrs	N	0	0	0	0	6
	Mean					402.4
	SD					22.7
	Median					405.3
	Minimum					364
	Maximum					424

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-19.2	-7.3	-7.0	-6.9
	SD	13.5	4.9	14.1	10.5
	Median	-15.3	-5.3	-1.2	-7.3
	Minimum	-37	-16	-31	-29
	Maximum	-1	-3	5	9
Day 1: Post 8 hrs	N	6	6	6	8
	Mean	382.6	398.8	388.9	393.7
	SD	20.6	21.1	20.9	17.4
	Median	378.3	410.7	385.7	399.0
	Minimum	352	363	360	357
	Maximum	406	414	423	412

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					12.8
	SD					15.5
	Median					8.5
	Minimum					-3
	Maximum					34
Day 2: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-10.2	-9.8	-6.3	-5.8
	SD	11.1	8.7	11.5	15.7
	Median	-7.5	-10.0	-7.3	-2.5
	Minimum	-24	-19	-19	-34
	Maximum	3	2	14	14
Day 2: Pre-dose	N	6	6	6	6
	Mean	392.4	417.4	403.6	401.1
	SD	27.5	29.4	23.6	23.5
	Median	390.7	422.3	405.2	403.7
	Minimum	358	369	368	365
	Maximum	431	453	433	430

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 2: Post 24 hrs	N	6	6	6	6	6
	Mean	399.2	384.8	417.3	400.0	407.7
	SD	36.4	19.0	44.4	31.7	31.4
	Median	388.5	384.0	403.5	403.0	414.8
	Minimum	352	359	380	364	359
	Maximum	446	415	501	430	439

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	6	6	6	6
	Mean	-0.4	8.8	8.3	1.7
	SD	12.1	10.9	8.5	14.8
	Median	-1.5	12.5	6.7	-0.8
	Minimum	-19	-8	-1	-17
	Maximum	15	21	20	23
Day 2: Post 24 hrs	N	0	0	0	10
	Mean				403.1
	SD				11.3
	Median				403.5
	Minimum				385
	Maximum				418

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	6	6	6	6	6
	Mean	-3.7	-1.5	12.3	-1.8	18.2
	SD	25.0	15.3	7.9	15.3	11.1
	Median	-13.5	2.0	14.0	1.0	17.0
	Minimum	-26	-21	1	-26	5
	Maximum	33	18	20	13	35
Day 3: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	0	0	0	10
	Mean				8.5
	SD				11.0
	Median				8.5
	Minimum				-15
	Maximum				24
Day 3: Pre-dose	N	6	5	6	6
	Mean	387.5	413.2	394.9	394.8
	SD	18.7	20.0	17.3	25.2
	Median	384.5	416.3	391.2	398.3
	Minimum	366	385	372	355
	Maximum	411	439	421	429

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4: Pre-dose	5.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
5.15	N	6	5	6	6
	Mean	-5.3	-3.3	-0.3	-4.6
	SD	16.2	6.9	23.9	12.9
	Median	-0.7	-5.3	8.3	-7.8
	Minimum	-27	-11	-42	-17
	Maximum	10	7	20	19
Day 4: Pre-dose	N	6	3	5	6
	Mean	383.9	415.1	403.3	395.5
	SD	24.4	18.6	11.9	25.9
	Median	381.8	407.3	406.7	391.8
	Minimum	360	402	387	363
	Maximum	422	436	419	431

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 5: Pre-dose	6.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
	Day 5: Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
6.15	N	6	3	5	6	
	Mean	-8.9	-7.1	9.0	-3.8	
	SD	12.8	10.3	21.4	14.0	
	Median	-9.0	-9.0	16.3	-6.5	
	Minimum	-28	-16	-27	-20	
	Maximum	10	4	26	15	
Day 5: Pre-dose	N	6	3	5	6	
	Mean	390.4	412.0	403.3	385.6	
	SD	26.5	13.3	16.7	26.0	
	Median	390.0	411.3	405.7	387.0	
	Minimum	361	399	379	355	
	Maximum	434	426	425	427	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 6: Pre-dose	7.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
7.15	N	6	3	5	6
	Mean	-2.4	-10.2	8.9	-13.8
	SD	18.3	3.1	20.2	14.8
	Median	1.2	-11.7	15.7	-15.5
	Minimum	-37	-12	-24	-31
	Maximum	17	-7	26	12
Day 6: Pre-dose	N	6	0	5	4
	Mean	387.4		397.8	391.5
	SD	26.7		10.9	25.1
	Median	382.3		393.7	391.2
	Minimum	356		384	362
	Maximum	421		409	421

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 7: Pre-dose	8.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
	8.15	N	6	0	5	4
		Mean	-5.4		3.5	-11.2
		SD	14.0		25.7	15.8
		Median	-7.0		8.7	-13.8
		Minimum	-28		-41	-25
		Maximum	12		23	8
Day 7: Pre-dose		N	6	0	5	4
		Mean	386.8		402.4	398.4
		SD	24.1		15.0	25.9
		Median	383.8		407.7	401.3
		Minimum	362		380	370
		Maximum	425		419	421

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)			Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8: Pre-dose	9.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QT INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
	9.15	N	6	0	5	4
		Mean	-6.0		8.1	-4.3
		SD	15.7		20.0	19.3
		Median	-4.0		16.3	-3.5
		Minimum	-36		-26	-25
		Maximum	7		25	15
Day 8: Pre-dose		N	6	0	5	4
		Mean	390.5		397.5	394.7
		SD	25.1		16.5	20.5
		Median	385.5		399.7	398.2
		Minimum	361		380	369
		Maximum	430		414	413

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec) Statistics		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	414.2	392.9	399.8	399.0	390.9
	SD	22.1	11.8	19.7	25.6	15.8
	Median	415.3	392.3	401.4	404.6	384.5
	Minimum	377	379	365	355	377
	Maximum	441	407	418	426	420
Day 0	N	6	6	6	6	6
	Mean	412.0	390.6	397.2	404.4	389.7
	SD	14.3	13.0	23.8	22.5	16.1
	Median	415.4	387.7	399.9	404.5	381.1
	Minimum	386	374	361	377	376
	Maximum	426	409	431	433	414

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
QTCF INTERVAL, AGGREGATE (msec)		Statistics			
Day -28 to -1	N	6	6	6	16
	Mean	394.4	384.9	401.3	402.5
	SD	15.5	20.0	6.6	18.4
	Median	394.1	390.7	400.6	402.8
	Minimum	376	352	394	361
	Maximum	419	405	413	429
Day 0	N	6	6	6	16
	Mean	387.6	392.5	399.7	403.2
	SD	16.7	14.6	16.5	17.6
	Median	387.5	396.8	394.4	404.7
	Minimum	368	372	385	377
	Maximum	411	407	426	431

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec) Statistics		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Pre-dose	N	6	6	6	6	6
	Mean	412.5	388.0	400.4	399.0	389.3
	SD	17.7	17.0	17.0	20.3	17.6
	Median	414.7	385.1	398.6	400.3	381.2
	Minimum	381	366	374	363	375
	Maximum	431	416	424	419	414
Day 1: Post 1 hr	N	0	0	0	0	6
	Mean					405.1
	SD					9.4
	Median					404.7
	Minimum					395
	Maximum					416

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1: Pre-dose	N	6	6	6	16
	Mean	395.6	398.5	392.4	399.2
	SD	22.1	12.4	16.2	16.4
	Median	400.2	401.6	387.3	401.3
	Minimum	362	379	376	369
	Maximum	418	410	420	417
Day 1: Post 1 hr	N	6	6	6	8
	Mean	391.9	407.1	405.2	393.2
	SD	16.3	15.0	16.4	13.6
	Median	391.6	407.1	399.1	393.8
	Minimum	366	382	391	374
	Maximum	410	424	433	412

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec) Statistics		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					15.7
	SD					13.0
	Median					14.8
	Minimum					3
	Maximum					37
Day 1: Post 2 hr	N	6	6	6	6	6
	Mean	414.8	396.5	415.8	431.0	412.3
	SD	14.3	12.4	18.9	19.6	14.2
	Median	417.8	400.9	415.7	428.6	415.5
	Minimum	389	378	385	403	394
	Maximum	428	408	436	458	426

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-3.7	8.7	12.8	-3.4
	SD	7.1	4.6	3.9	4.9
	Median	-7.1	8.6	13.9	-3.0
	Minimum	-11	3	5	-13
	Maximum	7	14	15	4
Day 1: Post 2 hr	N	6	6	6	16
	Mean	397.8	409.2	407.4	393.0
	SD	15.7	12.6	11.8	13.1
	Median	402.0	407.0	402.0	395.8
	Minimum	370	395	398	369
	Maximum	412	431	425	417

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	2.3	8.5	15.4	32.0	22.9
	SD	8.1	9.5	13.6	12.6	13.1
	Median	4.9	9.1	11.5	35.2	16.7
	Minimum	-11	-7	2	13	12
	Maximum	9	21	40	46	45
Day 1: Post 3 hr	N	0	0	0	0	6
	Mean					418.5
	SD					8.6
	Median					419.2
	Minimum					404
	Maximum					431

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	2.2	10.7	15.1	-6.1
	SD	9.4	7.6	6.4	9.1
	Median	-1.0	9.3	16.8	-6.4
	Minimum	-9	3	5	-23
	Maximum	18	22	24	17
Day 1: Post 3 hr	N	6	6	6	8
	Mean	398.2	405.4	414.2	396.0
	SD	16.2	27.8	17.1	13.1
	Median	402.4	409.8	410.6	395.6
	Minimum	374	355	395	380
	Maximum	415	436	435	415

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec) Statistics		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					29.2
	SD					15.5
	Median					31.4
	Minimum					3
	Maximum					46
Day 1: Post 4 hrs	N	6	6	6	6	6
	Mean	408.8	393.0	408.6	421.1	412.2
	SD	20.5	13.1	14.3	21.1	15.2
	Median	413.0	386.6	409.6	428.7	408.6
	Minimum	372	380	384	387	396
	Maximum	433	414	426	440	430

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	2.6	6.9	21.8	-0.7
	SD	6.5	25.8	7.4	3.8
	Median	3.2	15.2	20.8	-0.9
	Minimum	-6	-42	13	-7
	Maximum	11	30	31	5
Day 1: Post 4 hrs	N	6	6	6	16
	Mean	397.6	404.7	399.4	396.2
	SD	16.8	12.4	14.7	16.8
	Median	399.6	404.9	403.7	396.3
	Minimum	371	390	380	366
	Maximum	419	420	415	433

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-3.6	5.0	8.2	22.1	22.8
	SD	16.5	6.0	5.6	9.6	7.4
	Median	-4.8	4.3	7.3	22.3	19.9
	Minimum	-22	-2	3	5	17
	Maximum	22	15	18	31	37
Day 1: Post 5 hrs	N	0	0	0	0	6
	Mean					404.8
	SD					20.8
	Median					396.5
	Minimum					388
	Maximum					441

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	2.0	6.3	7.0	-3.0
	SD	6.7	8.1	8.7	13.2
	Median	1.6	8.5	7.3	-5.2
	Minimum	-7	-7	-5	-25
	Maximum	10	14	18	32
Day 1: Post 5 hrs	N	6	6	6	8
	Mean	392.7	395.8	394.0	389.9
	SD	17.4	13.3	12.9	12.3
	Median	397.6	397.4	396.7	390.0
	Minimum	367	380	378	377
	Maximum	415	415	410	415

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					15.4
	SD					6.4
	Median					13.4
	Minimum					9
	Maximum					27
Day 1: Post 6 hrs	N	6	6	6	6	6
	Mean	409.8	392.0	405.3	417.8	406.9
	SD	17.5	12.5	21.1	21.4	15.3
	Median	414.4	386.9	407.3	429.0	403.9
	Minimum	379	378	371	382	392
	Maximum	424	409	430	434	429

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-2.9	-2.6	1.6	-6.7
	SD	9.3	4.8	7.5	7.1
	Median	0.1	-4.2	1.2	-6.0
	Minimum	-17	-8	-10	-17
	Maximum	6	5	11	4
Day 1: Post 6 hrs	N	6	6	6	16
	Mean	391.8	399.6	397.0	398.3
	SD	17.4	17.6	17.0	14.7
	Median	398.3	406.3	398.3	400.5
	Minimum	369	378	375	375
	Maximum	407	415	417	420

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec) Statistics		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-2.7	4.0	4.9	18.8	17.6
	SD	11.9	8.9	5.6	13.2	6.6
	Median	-1.2	4.8	6.3	16.2	16.3
	Minimum	-23	-10	-3	1	10
	Maximum	13	13	11	40	30
Day 1: Post 8 hrs	N	0	0	0	0	6
	Mean					402.1
	SD					11.1
	Median					400.3
	Minimum					388
	Maximum					420

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
QTCF INTERVAL, AGGREGATE (msec)	Statistics				
Change from Pre-dose	N	6	6	6	16
	Mean	-3.8	1.1	4.6	-0.9
	SD	7.9	7.1	8.5	9.9
	Median	-4.5	2.6	4.3	-1.8
	Minimum	-13	-12	-7	-20
	Maximum	7	8	14	19
Day 1: Post 8 hrs	N	6	6	6	8
	Mean	394.5	396.5	397.1	398.6
	SD	15.5	14.3	17.1	13.6
	Median	396.3	400.0	395.3	399.8
	Minimum	368	378	378	381
	Maximum	412	413	424	419

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec) Statistics		Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					12.8
	SD					9.0
	Median					15.0
	Minimum					-2
	Maximum					21
Day 2: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-1.1	-2.0	4.7	1.9
	SD	8.8	6.2	3.1	4.5
	Median	-3.4	-1.6	4.8	1.4
	Minimum	-12	-9	1	-5
	Maximum	12	7	9	8
Day 2: Pre-dose	N	6	6	6	6
	Mean	399.3	405.4	402.6	396.2
	SD	16.8	16.4	18.4	17.2
	Median	403.8	402.3	402.0	391.7
	Minimum	376	387	379	380
	Maximum	417	428	425	421

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 2: Post 24 hrs	N	6	6	6	6	6
	Mean	412.8	399.0	407.4	406.6	399.0
	SD	17.1	18.4	18.5	17.3	20.8
	Median	414.4	398.9	410.9	409.2	395.3
	Minimum	383	378	376	380	376
	Maximum	429	421	430	430	426

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec) Statistics		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	6	6	6	6
	Mean	3.7	6.9	10.2	2.9
	SD	6.2	9.6	7.5	9.4
	Median	1.3	6.3	7.4	2.0
	Minimum	-2	-7	3	-6
	Maximum	14	19	21	20
Day 2: Post 24 hrs	N	0	0	0	10
	Mean				403.8
	SD				16.2
	Median				406.6
	Minimum				369
	Maximum				426

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	6	6	6	6	6
	Mean	0.3	11.0	7.0	7.6	9.6
	SD	6.6	18.1	6.7	8.6	6.0
	Median	-0.7	8.5	4.8	8.6	11.3
	Minimum	-8	-8	2	-3	1
	Maximum	11	42	20	17	18
Day 3: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)    Statistics		Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	0	0	0	10
	Mean				1.1
	SD				11.0
	Median				-0.3
	Minimum				-13
	Maximum				26
Day 3: Pre-dose	N	6	5	6	6
	Mean	402.3	406.5	401.5	394.1
	SD	16.0	14.8	15.8	12.9
	Median	402.1	408.8	398.7	391.1
	Minimum	381	390	381	380
	Maximum	421	422	423	414

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
5.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 4: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
QTCF INTERVAL, AGGREGATE (msec)			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
5.15	N		6	5	6	6
	Mean		6.8	7.8	9.1	0.8
	SD		8.1	7.7	4.2	4.4
	Median		5.6	12.9	9.3	0.8
	Minimum		-4	-1	3	-5
	Maximum		19	14	14	7
Day 4: Pre-dose	N		6	3	5	6
	Mean		399.5	405.0	407.5	394.5
	SD		18.6	21.2	13.0	13.4
	Median		403.1	411.6	405.1	390.4
	Minimum		369	381	391	377
	Maximum		422	422	421	412

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
6.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 5: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

		Treatment Group*			
QTCF INTERVAL, AGGREGATE (msec)		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
6.15	N	6	3	5	6
	Mean	3.9	3.3	12.8	1.2
	SD	7.6	10.8	7.4	7.0
	Median	5.2	6.0	15.2	-1.0
	Minimum	-10	-9	0	-5
	Maximum	11	13	18	12
Day 5: Pre-dose	N	6	3	5	6
	Mean	403.5	401.7	408.6	395.1
	SD	20.0	22.8	16.1	11.2
	Median	402.5	408.9	403.3	391.2
	Minimum	372	376	391	382
	Maximum	430	420	426	410

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
7.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 6: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

QTCF INTERVAL, AGGREGATE (msec)      Statistics			Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 6: Pre-dose	7.15	N	6	3	5	6
		Mean	7.9	0.1	13.9	1.8
		SD	8.5	12.4	5.9	7.3
		Median	9.3	3.3	14.9	2.5
		Minimum	-7	-14	7	-9
		Maximum	19	11	22	10
		N	6	0	5	4
		Mean	403.1		407.0	388.9
		SD	19.8		10.1	13.5
		Median	406.7		410.8	389.0
		Minimum	375		393	374
		Maximum	429		417	404

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
8.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 7: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
QTCF INTERVAL, AGGREGATE (msec)			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
8.15	N		6	0	5	4
	Mean		7.5		12.4	-7.5
	SD		6.3		10.8	10.0
	Median		9.2		13.6	-6.0
	Minimum		-4		-5	-21
	Maximum		13		24	2
Day 7: Pre-dose	N		6	0	5	4
	Mean		399.9		408.6	394.0
	SD		18.1		13.1	15.0
	Median		399.9		411.4	394.5
	Minimum		374		394	379
	Maximum		424		422	408

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*				
QTCF INTERVAL, AGGREGATE (msec)	Statistics		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
9.15	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						
Day 8: Pre-dose	N		0	0	0	0	0
	Mean						
	SD						
	Median						
	Minimum						
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

			Treatment Group*			
QTCF INTERVAL, AGGREGATE (msec)			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
9.15	N		6	0	5	4
	Mean		4.3		14.0	-2.4
	SD		7.9		9.6	8.7
	Median		5.8		17.6	-2.6
	Minimum		-11		0	-11
	Maximum		12		25	7
Day 8: Pre-dose	N		6	0	5	4
	Mean		399.7		403.9	396.2
	SD		20.3		12.1	13.2
	Median		399.5		408.7	397.3
	Minimum		367		387	382
	Maximum		423		415	409

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Mean	1005.2	1010.6	1035.9	959.6	1006.2
	SD	76.9	116.9	242.0	180.6	218.7
	Median	1025.7	977.20	1039.4	949.60	911.59
	Minimum	870	909	732	741	874
	Maximum	1071	1200	1395	1250	1441
Day 0	N	6	6	6	6	6
	Mean	984.3	908.3	1012.0	943.6	982.7
	SD	61.0	187.1	241.1	63.9	187.6
	Median	1000.0	930.25	945.35	952.60	925.39
	Minimum	870	645	789	857	841
	Maximum	1053	1132	1463	1017	1334

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.2.ecg.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Mean	907.4	974.2	1017.8	978.1
	SD	66.3	151.3	49.9	114.3
	Median	883.37	1012.2	1014.2	1000.3
	Minimum	859	679	947	764
	Maximum	1030	1111	1075	1176
Day 0	N	6	6	6	16
	Mean	887.3	1002.3	1043.9	999.4
	SD	109.2	164.6	122.3	109.8
	Median	873.57	1088.0	1020.4	1032.0
	Minimum	776	698	928	803
	Maximum	1048	1108	1251	1139

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Pre-dose	N	6	6	6	6	6
	Mean	936.4	994.6	1041.4	1029.3	1010.9
	SD	107.2	153.8	223.9	148.3	196.8
	Median	952.60	1004.5	983.60	1072.8	933.19
	Minimum	759	750	857	759	847
	Maximum	1071	1154	1463	1176	1375
Day 1: Post 1 hr	N	0	0	0	0	6
	Mean					1059.6
	SD					200.3
	Median					1027.3
	Minimum					852
	Maximum					1429

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1: Pre-dose	N	6	6	6	16
	Mean	983.1	1083.8	1024.9	988.5
	SD	102.4	145.6	117.3	151.3
	Median	979.49	1150.5	1050.6	960.55
	Minimum	887	801	876	800
	Maximum	1169	1178	1154	1277
Day 1: Post 1 hr	N	6	6	6	8
	Mean	969.8	1126.3	1049.8	1032.9
	SD	101.5	171.0	117.9	132.7
	Median	965.97	1165.1	1035.6	1030.8
	Minimum	804	802	928	849
	Maximum	1098	1314	1242	1201

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					48.6
	SD					70.4
	Median					29.04
	Minimum					-7
	Maximum					183
Day 1: Post 2 hr	N	6	6	6	6	6
	Mean	993.4	963.7	1082.4	968.2	1060.0
	SD	73.8	196.9	278.0	93.0	204.0
	Median	967.95	937.25	1047.4	1008.5	1040.5
	Minimum	923	732	822	800	835
	Maximum	1111	1200	1579	1053	1441

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-13.3	42.5	24.9	5.8
	SD	60.3	70.2	53.2	57.0
	Median	-13.52	22.19	29.50	4.05
	Minimum	-83	-42	-66	-54
	Maximum	56	145	88	109
Day 1: Post 2 hr	N	6	6	6	16
	Mean	981.4	1148.4	1106.1	1054.2
	SD	110.5	187.1	146.1	123.4
	Median	963.17	1165.5	1122.9	1084.5
	Minimum	830	811	933	857
	Maximum	1112	1374	1268	1225

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	57.0	-31.0	41.0	-61.1	49.1
	SD	62.6	102.3	71.9	92.8	69.2
	Median	47.45	1.50	31.45	-102.6	64.33
	Minimum	-16	-191	-48	-160	-44
	Maximum	164	72	127	69	151
Day 1: Post 3 hr	N	0	0	0	0	6
	Mean					1006.4
	SD					189.4
	Median					941.20
	Minimum					823
	Maximum					1346

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-1.6	64.6	81.3	65.7
	SD	85.5	74.7	37.9	86.3
	Median	-42.12	43.56	71.80	67.77
	Minimum	-75	7	28	-100
	Maximum	137	205	135	253
Day 1: Post 3 hr	N	6	6	6	8
	Mean	910.2	1063.8	897.4	979.6
	SD	97.6	169.5	58.6	98.8
	Median	924.24	1126.0	902.72	975.70
	Minimum	735	753	793	861
	Maximum	1018	1220	956	1105

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-4.5
	SD					45.5
	Median					-3.40
	Minimum					-75
	Maximum					43
Day 1: Post 4 hrs	N	6	6	6	6	6
	Mean	926.8	921.2	961.6	941.0	980.6
	SD	95.0	135.8	170.0	124.4	128.0
	Median	923.90	912.40	952.30	976.15	975.34
	Minimum	779	759	769	723	791
	Maximum	1034	1071	1224	1071	1154

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-72.9	-20.0	-127.4	-47.5
	SD	78.3	88.0	130.3	64.6
	Median	-81.09	-38.97	-122.5	-34.39
	Minimum	-152	-143	-314	-128
	Maximum	46	108	20	47
Day 1: Post 4 hrs	N	6	6	6	16
	Mean	848.0	1034.5	921.1	946.8
	SD	101.7	164.9	59.9	97.0
	Median	850.62	1063.6	900.49	952.60
	Minimum	732	729	861	789
	Maximum	1029	1218	1011	1132

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-9.6	-73.4	-79.8	-88.4	-30.4
	SD	129.0	91.3	83.2	82.1	100.6
	Median	-34.95	-70.50	-44.20	-88.15	5.40
	Minimum	-158	-186	-239	-229	-221
	Maximum	152	50	-20	16	53
Day 1: Post 5 hrs	N	0	0	0	0	6
	Mean					1023.6
	SD					114.7
	Median					1024.3
	Minimum					874
	Maximum					1179

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-135.1	-49.4	-103.8	-41.7
	SD	13.3	77.7	87.7	97.3
	Median	-137.4	-72.70	-85.51	-50.24
	Minimum	-155	-133	-235	-204
	Maximum	-120	48	-15	146
Day 1: Post 5 hrs	N	6	6	6	8
	Mean	893.3	1056.4	948.1	1006.6
	SD	121.3	165.9	83.5	85.3
	Median	889.95	1079.8	957.93	1020.1
	Minimum	713	760	833	823
	Maximum	1072	1233	1066	1092

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					12.6
	SD					109.9
	Median					41.32
	Minimum					-197
	Maximum					123
Day 1: Post 6 hrs	N	6	6	6	6	6
	Mean	902.4	878.5	949.9	923.8	1018.1
	SD	14.2	128.7	133.1	110.6	135.0
	Median	902.25	854.50	923.90	937.50	993.00
	Minimum	882	750	800	723	854
	Maximum	923	1053	1154	1053	1242

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-89.8	-27.4	-76.8	-20.5
	SD	83.9	53.5	57.2	119.2
	Median	-112.8	-39.15	-47.17	-51.82
	Minimum	-174	-99	-159	-192
	Maximum	66	64	-27	174
Day 1: Post 6 hrs	N	6	6	6	16
	Mean	870.4	1021.5	937.5	939.4
	SD	86.7	151.8	83.9	113.0
	Median	884.67	1010.3	929.37	947.37
	Minimum	726	774	800	714
	Maximum	961	1242	1029	1185

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	6	6	6	6	6
	Mean	-34.0	-116.1	-91.5	-105.5	7.2
	SD	112.9	85.0	137.5	115.4	73.9
	Median	-63.70	-108.5	-50.40	-112.2	25.85
	Minimum	-162	-245	-310	-267	-133
	Maximum	164	0	69	69	66
Day 1: Post 8 hrs	N	0	0	0	0	6
	Mean					1007.1
	SD					135.4
	Median					1031.8
	Minimum					773
	Maximum					1177

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	16
	Mean	-112.7	-62.3	-87.3	-49.1
	SD	105.5	82.3	64.4	82.3
	Median	-139.9	-65.25	-79.96	-49.60
	Minimum	-241	-150	-181	-242
	Maximum	68	73	9	80
Day 1: Post 8 hrs	N	6	6	6	8
	Mean	913.5	1027.8	939.1	965.8
	SD	69.7	166.3	49.4	84.2
	Median	913.93	1044.4	937.70	979.49
	Minimum	815	754	865	822
	Maximum	1012	1268	995	1078

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Pre-dose	N	0	0	0	0	6
	Mean					-3.8
	SD					128.0
	Median					4.73
	Minimum					-198
	Maximum					138
Day 2: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Pre-dose	N	6	6	6	8
	Mean	-69.6	-56.0	-85.8	-61.3
	SD	77.3	92.8	77.5	105.9
	Median	-89.55	-65.42	-88.98	-51.42
	Minimum	-158	-161	-166	-278
	Maximum	60	98	33	53
Day 2: Pre-dose	N	6	6	6	6
	Mean	954.4	1099.7	1007.5	1040.0
	SD	142.5	169.0	70.7	106.2
	Median	945.65	1133.4	1011.8	1031.8
	Minimum	770	774	918	883
	Maximum	1185	1261	1105	1178

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					
Day 2: Post 24 hrs	N	6	6	6	6	6
	Mean	907.5	904.9	1088.8	955.7	1073.0
	SD	156.7	135.7	271.1	143.3	160.8
	Median	846.55	857.80	1071.4	941.15	1057.5
	Minimum	769	759	822	759	873
	Maximum	1132	1091	1579	1132	1354

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	6	6	6	6
	Mean	-28.7	15.9	-17.4	-11.2
	SD	87.0	48.6	58.9	80.2
	Median	-25.50	0.00	-16.44	-26.89
	Minimum	-128	-27	-101	-97
	Maximum	75	92	62	142
Day 2: Post 24 hrs	N	0	0	0	10
	Mean				1000.9
	SD				110.2
	Median				1017.2
	Minimum				845
	Maximum				1154

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Change from Day 1: Pre-dose	N	6	6	6	6	6
	Mean	-28.9	-89.7	47.4	-73.7	62.1
	SD	172.0	94.0	80.3	99.6	67.2
	Median	-73.55	-71.15	43.90	-32.30	61.92
	Minimum	-189	-261	-48	-229	-22
	Maximum	250	9	148	16	138
Day 3: Pre-dose	N	0	0	0	0	0
	Mean					
	SD					
	Median					
	Minimum					
	Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Change from Day 1: Pre-dose	N	0	0	0	10
	Mean				50.0
	SD				105.1
	Median				68.95
	Minimum				-145
	Maximum				200
Day 3: Pre-dose	N	6	5	6	6
	Mean	898.6	1053.1	955.6	1007.7
	SD	82.8	82.9	94.5	116.2
	Median	926.84	1084.4	958.67	996.27
	Minimum	740	947	793	811
	Maximum	974	1125	1065	1134

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 4: Pre-dose	5.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
5.15	N	6	5	6	6	
	Mean	-84.5	-87.2	-69.2	-43.5	
	SD	97.5	45.6	151.9	87.5	
	Median	-76.24	-76.93	-12.29	-76.75	
	Minimum	-232	-156	-313	-112	
	Maximum	41	-44	77	127	
Day 4: Pre-dose	N	6	3	5	6	
	Mean	891.7	1082.2	970.8	1010.3	
	SD	115.7	100.6	36.3	122.7	
	Median	869.93	1104.8	978.47	1036.3	
	Minimum	772	972	913	794	
	Maximum	1071	1169	1011	1143	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 5: Pre-dose	6.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
	Day 5: Pre-dose	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
6.15	N	6	3	5	6	
	Mean	-91.3	-79.9	-28.2	-40.9	
	SD	59.6	84.0	121.1	92.6	
	Median	-89.51	-72.77	-10.76	-85.42	
	Minimum	-186	-167	-194	-122	
	Maximum	-7	0	103	98	
Day 5: Pre-dose	N	6	3	5	6	
	Mean	913.9	1083.8	962.7	933.7	
	SD	144.5	94.5	58.4	133.9	
	Median	936.05	1040.5	995.23	934.37	
	Minimum	695	1019	887	755	
	Maximum	1118	1192	1018	1147	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 6: Pre-dose	7.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
	Maximum						

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
7.15	N	6	3	5	6	
	Mean	-69.2	-78.4	-36.3	-117.5	
	SD	63.4	88.1	127.8	126.4	
	Median	-51.32	-120.9	5.47	-132.7	
	Minimum	-191	-137	-220	-234	
	Maximum	-11	23	120	109	
Day 6: Pre-dose	N	6	0	5	4	
	Mean	891.1		934.4	1022.8	
	SD	104.2		50.2	124.9	
	Median	884.95		944.00	990.52	
	Minimum	735		853	910	
	Maximum	1052		990	1200	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 7: Pre-dose	8.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
8.15	N	6	0	5	4	
	Mean	-92.0		-64.6	-29.3	
	SD	62.3		130.3	122.7	
	Median	-117.0		-50.53	-39.92	
	Minimum	-152		-254	-168	
	Maximum	3		77	131	
Day 7: Pre-dose	N	6	0	5	4	
	Mean	910.8		955.4	1033.4	
	SD	126.1		44.7	86.5	
	Median	918.24		978.30	1042.5	
	Minimum	723		900	928	
	Maximum	1085		995	1121	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8: Pre-dose	9.15	N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					
		N	0	0	0	0	0
		Mean					
		SD					
		Median					
		Minimum					
		Maximum					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Protocol: LB-102-001

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Table 14.3.5.2 - Electrocardiogram (ECG)

RR INTERVAL, AGGREGATE (msec)		Statistics	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
9.15	N	6	0	5	4	
	Mean	-72.3		-43.6	-18.8	
	SD	60.7		119.7	132.2	
	Median	-73.17		-16.23	-24.98	
	Minimum	-164		-192	-150	
	Maximum	19		119	125	
Day 8: Pre-dose	N	6	0	5	4	
	Mean	935.5		953.3	989.2	
	SD	108.2		55.4	57.2	
	Median	918.45		942.53	1006.8	
	Minimum	797		897	909	
	Maximum	1098		1029	1035	

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	4 ( 66.7%)	2 ( 33.3%)	2 ( 33.3%)	2 ( 33.3%)	3 ( 50.0%)
	Abnormal	2 ( 33.3%)	4 ( 66.7%)	4 ( 66.7%)	4 ( 66.7%)	3 ( 50.0%)
Day 0	N	6	6	6	6	6
	Normal	4 ( 66.7%)	4 ( 66.7%)	2 ( 33.3%)	1 ( 16.7%)	3 ( 50.0%)
	Abnormal	2 ( 33.3%)	2 ( 33.3%)	4 ( 66.7%)	5 ( 83.3%)	3 ( 50.0%)
Day 1: Pre-dose	N	6	6	6	6	6
	Normal	4 ( 66.7%)	2 ( 33.3%)	3 ( 50.0%)	3 ( 50.0%)	2 ( 33.3%)
	Abnormal	2 ( 33.3%)	4 ( 66.7%)	3 ( 50.0%)	3 ( 50.0%)	4 ( 66.7%)
Day 1: Post 1 hr	N	0	0	0	0	6
	Normal					2 ( 33.3%)
	Abnormal					4 ( 66.7%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	1 ( 16.7%)	3 ( 50.0%)	3 ( 50.0%)	10 ( 62.5%)
	Abnormal	5 ( 83.3%)	3 ( 50.0%)	3 ( 50.0%)	6 ( 37.5%)
Day 0	N	6	6	6	16
	Normal	2 ( 33.3%)	4 ( 66.7%)	3 ( 50.0%)	8 ( 50.0%)
	Abnormal	4 ( 66.7%)	2 ( 33.3%)	3 ( 50.0%)	8 ( 50.0%)
Day 1: Pre-dose	N	6	6	6	16
	Normal	1 ( 16.7%)	3 ( 50.0%)	2 ( 33.3%)	8 ( 50.0%)
	Abnormal	5 ( 83.3%)	3 ( 50.0%)	4 ( 66.7%)	8 ( 50.0%)
Day 1: Post 1 hr	N	6	6	6	8
	Normal	3 ( 50.0%)	4 ( 66.7%)	4 ( 66.7%)	2 ( 25.0%)
	Abnormal	3 ( 50.0%)	2 ( 33.3%)	2 ( 33.3%)	6 ( 75.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Post 2 hr	N	6	6	6	6	6
	Normal	4 ( 66.7%)	2 ( 33.3%)	3 ( 50.0%)	1 ( 16.7%)	1 ( 16.7%)
	Abnormal	2 ( 33.3%)	4 ( 66.7%)	3 ( 50.0%)	5 ( 83.3%)	5 ( 83.3%)
Day 1: Post 3 hr	N	0	0	0	0	6
	Normal					1 ( 16.7%)
	Abnormal					5 ( 83.3%)
Day 1: Post 4 hrs	N	6	6	6	6	6
	Normal	3 ( 50.0%)	4 ( 66.7%)	1 ( 16.7%)	1 ( 16.7%)	1 ( 16.7%)
	Abnormal	3 ( 50.0%)	2 ( 33.3%)	5 ( 83.3%)	5 ( 83.3%)	5 ( 83.3%)
Day 1: Post 5 hrs	N	0	0	0	0	6
	Normal					2 ( 33.3%)
	Abnormal					4 ( 66.7%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1: Post 2 hr	N	6	6	6	16
	Normal	3 ( 50.0%)	4 ( 66.7%)	3 ( 50.0%)	8 ( 50.0%)
	Abnormal	3 ( 50.0%)	2 ( 33.3%)	3 ( 50.0%)	8 ( 50.0%)
Day 1: Post 3 hr	N	6	6	6	8
	Normal	0 ( 0.0%)	1 ( 16.7%)	3 ( 50.0%)	3 ( 37.5%)
	Abnormal	6 (100.0%)	5 ( 83.3%)	3 ( 50.0%)	5 ( 62.5%)
Day 1: Post 4 hrs	N	6	6	6	16
	Normal	1 ( 16.7%)	0 ( 0.0%)	3 ( 50.0%)	8 ( 50.0%)
	Abnormal	5 ( 83.3%)	6 (100.0%)	3 ( 50.0%)	8 ( 50.0%)
Day 1: Post 5 hrs	N	6	6	6	8
	Normal	1 ( 16.7%)	2 ( 33.3%)	2 ( 33.3%)	3 ( 37.5%)
	Abnormal	5 ( 83.3%)	4 ( 66.7%)	4 ( 66.7%)	5 ( 62.5%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 1: Post 6 hrs	N	6	6	6	6	6
	Normal	4 ( 66.7%)	4 ( 66.7%)	2 ( 33.3%)	2 ( 33.3%)	1 ( 16.7%)
	Abnormal	2 ( 33.3%)	2 ( 33.3%)	4 ( 66.7%)	4 ( 66.7%)	5 ( 83.3%)
Day 1: Post 8 hrs	N	0	0	0	0	6
	Normal					2 ( 33.3%)
	Abnormal					4 ( 66.7%)
Day 2: Pre-dose	N	0	0	0	0	0
	Normal					
	Abnormal					
Day 2: Post 24 hrs	N	6	6	6	6	6
	Normal	4 ( 66.7%)	4 ( 66.7%)	2 ( 33.3%)	0 ( 0.0%)	2 ( 33.3%)
	Abnormal	2 ( 33.3%)	2 ( 33.3%)	4 ( 66.7%)	6 (100.0%)	4 ( 66.7%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 1: Post 6 hrs	N	6	6	6	16
	Normal	1 ( 16.7%)	1 ( 16.7%)	3 ( 50.0%)	9 ( 56.3%)
	Abnormal	5 ( 83.3%)	5 ( 83.3%)	3 ( 50.0%)	7 ( 43.8%)
Day 1: Post 8 hrs	N	6	6	6	8
	Normal	2 ( 33.3%)	0 ( 0.0%)	3 ( 50.0%)	3 ( 37.5%)
	Abnormal	4 ( 66.7%)	6 (100.0%)	3 ( 50.0%)	5 ( 62.5%)
Day 2: Pre-dose	N	6	6	6	6
	Normal	2 ( 33.3%)	3 ( 50.0%)	2 ( 33.3%)	2 ( 33.3%)
	Abnormal	4 ( 66.7%)	3 ( 50.0%)	4 ( 66.7%)	4 ( 66.7%)
Day 2: Post 24 hrs	N	0	0	0	10
	Normal				6 ( 60.0%)
	Abnormal				4 ( 40.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 3: Pre-dose	N	0	0	0	0	0
	Normal					
	Abnormal					
Day 4: Pre-dose	N	0	0	0	0	0
	Normal					
	Abnormal					
Day 5: Pre-dose	N	0	0	0	0	0
	Normal					
	Abnormal					
Day 6: Pre-dose	N	0	0	0	0	0
	Normal					
	Abnormal					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 3: Pre-dose	N	6	5	6	6
	Normal	0 ( 0.0%)	2 ( 40.0%)	2 ( 33.3%)	2 ( 33.3%)
	Abnormal	6 (100.0%)	3 ( 60.0%)	4 ( 66.7%)	4 ( 66.7%)
Day 4: Pre-dose	N	6	3	5	6
	Normal	1 ( 16.7%)	2 ( 66.7%)	2 ( 40.0%)	2 ( 33.3%)
	Abnormal	5 ( 83.3%)	1 ( 33.3%)	3 ( 60.0%)	4 ( 66.7%)
Day 5: Pre-dose	N	6	3	5	6
	Normal	1 ( 16.7%)	1 ( 33.3%)	3 ( 60.0%)	3 ( 50.0%)
	Abnormal	5 ( 83.3%)	2 ( 66.7%)	2 ( 40.0%)	3 ( 50.0%)
Day 6: Pre-dose	N	6	0	5	4
	Normal	2 ( 33.3%)		4 ( 80.0%)	2 ( 50.0%)
	Abnormal	4 ( 66.7%)		1 ( 20.0%)	2 ( 50.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 7: Pre-dose	N	0	0	0	0	0
	Normal					
	Abnormal					
Day 8: Pre-dose	N	0	0	0	0	0
	Normal					
	Abnormal					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.2 - Electrocardiogram (ECG)

INTERPRETATION	Statistics	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 7: Pre-dose	N	6	0	5	4
	Normal	1 ( 16.7%)		2 ( 40.0%)	1 ( 25.0%)
	Abnormal	5 ( 83.3%)		3 ( 60.0%)	3 ( 75.0%)
Day 8: Pre-dose	N	6	0	5	4
	Normal	0 ( 0.0%)		4 ( 80.0%)	1 ( 25.0%)
	Abnormal	6 (100.0%)		1 ( 20.0%)	3 ( 75.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Abdominal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.3.1 - Physical Examinations

Cardiovascular	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	14 ( 87.5%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 12.5%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	14 ( 87.5%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 12.5%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	5 ( 83.3%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	12 ( 85.7%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 14.3%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	2 ( 50.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 50.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Ears	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	5 ( 83.3%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Eyes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Head	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Head	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Head	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Head	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Head	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Head	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.5.3.1 - Physical Examinations

Heart	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
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Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Lungs	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Lymph Nodes	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	15 ( 93.8%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 6.3%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Musculoskeletal	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neck	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.5.3.1 - Physical Examinations

Neurologic	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas



LB Pharmaceuticals, Inc.  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

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Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Nose	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	4 ( 66.7%)	5 ( 83.3%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)
	Abnormal - NCS	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	4 ( 66.7%)	5 ( 83.3%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)
	Abnormal - NCS	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	3 ( 50.0%)	3 ( 50.0%)	5 ( 83.3%)	14 ( 87.5%)
	Abnormal - NCS	3 ( 50.0%)	3 ( 50.0%)	1 ( 16.7%)	2 ( 12.5%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	3 ( 50.0%)	3 ( 50.0%)	5 ( 83.3%)	14 ( 87.5%)
	Abnormal - NCS	3 ( 50.0%)	3 ( 50.0%)	1 ( 16.7%)	2 ( 12.5%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	4 ( 66.7%)	5 ( 83.3%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)
	Abnormal - NCS	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	3 ( 50.0%)	3 ( 50.0%)	5 ( 83.3%)	14 ( 87.5%)
	Abnormal - NCS	3 ( 50.0%)	3 ( 50.0%)	1 ( 16.7%)	2 ( 12.5%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	3 ( 50.0%)	1 ( 33.3%)	4 ( 80.0%)	6 (100.0%)
	Abnormal - NCS	3 ( 50.0%)	2 ( 66.7%)	1 ( 20.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	4 ( 66.7%)	5 ( 83.3%)	6 (100.0%)	5 ( 83.3%)	6 (100.0%)
	Abnormal - NCS	2 ( 33.3%)	1 ( 16.7%)	0 ( 0.0%)	1 ( 16.7%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	3 ( 50.0%)	0 ( 0.0%)	4 ( 80.0%)	11 ( 78.6%)
	Abnormal - NCS	3 ( 50.0%)	0 ( 0.0%)	1 ( 20.0%)	3 ( 21.4%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	3 ( 50.0%)	0 ( 0.0%)	4 ( 80.0%)	4 (100.0%)
	Abnormal - NCS	3 ( 50.0%)	0 ( 0.0%)	1 ( 20.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Skin	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	2 ( 66.7%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	1 ( 33.3%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.1.pe.sas



LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Throat	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day -28 to -1	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day -28 to -1	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 0	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 2	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 2	N	6	6	6	16
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 4	N	6	3	5	6
	Normal	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Day 8	N	6	6	6	6	6
	Normal	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Day 8	N	6	0	5	14
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	14 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
Day 15	N	6	0	5	4
	Normal	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*				
		Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
EARLY TERMINATION	N	0	0	0	0	0
	Normal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.1 - Physical Examinations

Thyroid	Results	Treatment Group*			
		Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
EARLY TERMINATION	N	0	3	1	0
	Normal	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)
	Abnormal - NCS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Abnormal - CS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Not Done	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Abdominal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Abdominal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Abdominal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Abdominal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Cardiovascular		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Cardiovascular		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Cardiovascular		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Cardiovascular		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Ears		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Ears		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Ears		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	14	0
	Abnormal*	0	0	0	0	0	0	0	2
Day 4	Normal	6	0	3	0	5	0	4	1
	Abnormal*	0	0	0	0	0	0	0	1
Day 8	Normal	6	0	0	0	5	0	12	0
	Abnormal*	0	0	0	0	0	0	0	2
Day 15	Normal	6	0	0	0	5	0	2	0
	Abnormal*	0	0	0	0	0	0	0	2

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Ears		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Eyes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Eyes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6		Cohort 7		Cohort 8		Placebo	
		(N = 6)		(N = 6)		(N = 6)		(N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Eyes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	5	0
	Abnormal*	0	0	0	0	0	0	1	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Eyes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Head		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Head		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6		Cohort 7		Cohort 8		Placebo	
		(N = 6)		(N = 6)		(N = 6)		(N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Head		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Head		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Heart		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Heart		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6		Cohort 7		Cohort 8		Placebo	
		(N = 6)		(N = 6)		(N = 6)		(N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Heart		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Heart		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Lungs		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Lungs		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Lungs		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Lungs		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Lymph Nodes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Lymph Nodes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Lymph Nodes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Lymph Nodes		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Musculoskeletal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Musculoskeletal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Musculoskeletal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	15	0
	Abnormal*	0	0	0	0	0	0	1	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Musculoskeletal		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Neck		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Neck		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Neck		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Neck		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Neurologic		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Neurologic		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Neurologic		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Neurologic		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Nose		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	5	0	6	0	6	0
	Abnormal*	0	0	0	0	1	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Nose		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Nose		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Nose		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Skin		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	4	0	5	0	6	0	5	0	6	0
	Abnormal*	0	2	0	1	0	0	0	1	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	4	0	5	0	6	0	5	0	6	0
	Abnormal*	0	2	0	1	0	0	0	1	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Skin		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Skin		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	3	0	3	0	5	0	14	0
	Abnormal*	0	3	0	3	0	1	0	2
Day 4	Normal	3	0	1	0	4	0	6	0
	Abnormal*	0	3	0	2	0	1	0	0
Day 8	Normal	3	0	0	0	4	0	11	0
	Abnormal*	0	3	0	0	0	1	1	2
Day 15	Normal	3	0	0	0	4	0	4	0
	Abnormal*	0	3	0	0	0	1	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Skin		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	2	0	1	0	0	0
	Abnormal*	0	0	0	1	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas



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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Throat		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.3.2.pe\_shift.sas

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Throat		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Throat		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Throat		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1 (N = 6)		Cohort 2 (N = 6)		Cohort 3 (N = 6)		Cohort 4 (N = 6)		Cohort 5 (N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Thyroid		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 4	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	6	0	6	0	6	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0
Day 15	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**									
		Cohort 1		Cohort 2		Cohort 3		Cohort 4		Cohort 5	
		(N = 6)		(N = 6)		(N = 6)		(N = 6)		(N = 6)	
		Baseline		Baseline		Baseline		Baseline		Baseline	
Thyroid		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	0	0	0	0	0	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Thyroid		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Day 2	Normal	6	0	6	0	6	0	16	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 4	Normal	6	0	3	0	5	0	6	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 8	Normal	6	0	0	0	5	0	14	0
	Abnormal*	0	0	0	0	0	0	0	0
Day 15	Normal	6	0	0	0	5	0	4	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.3.2 - Physical Examinations - Shift from Baseline

		Treatment Group**							
		Cohort 6 (N = 6)		Cohort 7 (N = 6)		Cohort 8 (N = 6)		Placebo (N = 16)	
		Baseline		Baseline		Baseline		Baseline	
Thyroid		Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Early Termination	Normal	0	0	3	0	1	0	0	0
	Abnormal*	0	0	0	0	0	0	0	0

\* Abnormal - NCS

\*\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.4 - Concomitant Medications

MEDICATION CLASS / STANDARDIZED NAMES	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
ANILIDES					
NYQUIL	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
PARACETAMOL	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ETHERS CHEMICALLY CLOSE TO ANTIHISTAMINES					
DIPHENHYDRAMINE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
ETHERS OF TROPINE OR TROPINE DERIVATIVES					
BENZATROPINE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
GLUCOCORTICOIDS					
METHYLPREDNISOLONE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
HYPNOTICS AND SEDATIVES					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.4.cm.sas

LB Pharmaceuticals, Inc.  
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Table 14.3.5.4 - Concomitant Medications

MEDICATION CLASS / STANDARDIZED NAMES	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
ANILIDES				
NYQUIL	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PARACETAMOL	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 (12.5%)
ETHERS CHEMICALLY CLOSE TO ANTIHISTAMINES				
DIPHENHYDRAMINE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ETHERS OF TROPINE OR TROPINE DERIVATIVES				
BENZATROPINE	0 ( 0.0%)	1 (16.7%)	1 (16.7%)	0 ( 0.0%)
GLUCOCORTICOIDS				
METHYLPREDNISOLONE	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
HYPNOTICS AND SEDATIVES				

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.4.cm.sas

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Table 14.3.5.4 - Concomitant Medications

MEDICATION CLASS / STANDARDIZED NAMES	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
PROMETHAZINE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
MULTIVITAMINS, PLAIN VITAMINS NOS	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE ACRIVASTINE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PIPERAZINE DERIVATIVES CETIRIZINE	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
PROGESTOGENS ETONOGESTREL	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS					

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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LB Pharmaceuticals, Inc.  
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Table 14.3.5.4 - Concomitant Medications

MEDICATION CLASS / STANDARDIZED NAMES	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
PROMETHAZINE	0 ( 0.0%)	1 (16.7%)	1 (16.7%)	0 ( 0.0%)
MULTIVITAMINS, PLAIN VITAMINS NOS	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE ACRIVASTINE	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
PIPERAZINE DERIVATIVES CETIRIZINE	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PROGESTOGENS ETONOGESTREL	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS				

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.4 - Concomitant Medications

MEDICATION CLASS / STANDARDIZED NAMES	Treatment Group*				
	Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
DROSPIRENONE;ETHINYLESTRADIOL	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ETHINYLESTRADIOL;LEVONORGESTREL	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)
PROPIONIC ACID DERIVATIVES					
IBUPROFEN	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
SEROTONIN (5HT3) ANTAGONISTS					
ONDANSETRON	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.4 - Concomitant Medications

MEDICATION CLASS / STANDARDIZED NAMES	Treatment Group*			
	Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
DROSPIRENONE;ETHINYLESTRADIOL	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
ETHINYLESTRADIOL;LEVONORGESTREL	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
PROPIONIC ACID DERIVATIVES				
IBUPROFEN	0 ( 0.0%)	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)
SEROTONIN (5HT3) ANTAGONISTS				
ONDANSETRON	0 ( 0.0%)	1 (16.7%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you wished you were dead or wished you could go to sleep and not wake up in lifetime?	Day -28 to -1	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Have you actually had any thoughts of killing yourself in lifetime?	Day -28 to -1	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you wished you were dead or wished you could go to sleep and not wake up since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you wished you were dead or wished you could go to sleep and not wake up in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Have you actually had any thoughts of killing yourself in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Have you wished you were dead or wished you could go to sleep and not wake up since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you wished you were dead or wished you could go to sleep and not wake up since last visit?	Day 3	No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you made a suicide attempt in lifetime?	Day -28 to -1	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Has subject engaged in Non-Suicidal Self-Injurious Behavior in lifetime?	Day -28 to -1	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Have you wished you were dead or wished you could go to sleep and not wake up since last visit?	Day 8	N	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you wished you were dead or wished you could go to sleep and not wake up since last visit?	Day 8	Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you made a suicide attempt in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Has subject engaged in Non-Suicidal Self-Injurious Behavior in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Have you wished you were dead or wished you could go to sleep and not wake up since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you wished you were dead or wished you could go to sleep and not wake up since last visit?	Day 8	No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything in lifetime?	Day -28 to -1	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything in lifetime?	Day -28 to -1	N	6	6	6	6	6

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything in lifetime?	Day -28 to -1	Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Have you actually had any thoughts of killing yourself since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you actually had any thoughts of killing yourself since last visit?	Day 4	Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

Program: 14.3.5.5.cssrs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you actually had any thoughts of killing yourself since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note) in lifetime?	Day -28 to -1	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
Suicidal behavior was present during the assessment period in lifetime?	Day -28 to -1	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you actually had any thoughts of killing yourself since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note) in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)
Suicidal behavior was present during the assessment period in lifetime?	Day -28 to -1	N	6	6	6	16
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	16 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you actually had any thoughts of killing yourself since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you made a suicide attempt since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you made a suicide attempt since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you made a suicide attempt since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you made a suicide attempt since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has subject engaged in Non-Suicidal Self-Injurious Behavior since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has subject engaged in Non-Suicidal Self-Injurious Behavior since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has subject engaged in Non-Suicidal Self-Injurious Behavior since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has subject engaged in Non-Suicidal Self-Injurious Behavior since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.5.cssrs.sas

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day); Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day); Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day); And Placebo (all cohorts combined).

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C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note) since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note) since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note) since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note) since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Suicidal behavior was present during the assessment period since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Suicidal behavior was present during the assessment period since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Suicidal behavior was present during the assessment period since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
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C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Suicidal behavior was present during the assessment period since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.5.cssrs.sas

LB Pharmaceuticals, Inc.  
Protocol: LB-102-001

A Randomized, Double-Blinded, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of LB-102 Administered Orally to Healthy Subjects

Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has subject completed Suicide since last visit?	Day 3	N	6	6	6	6	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
	Day 4	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.5.cssrs.sas



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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has subject completed Suicide since last visit?	Day 3	N	0	0	0	10
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	10 (100.0%)
	Day 4	N	6	3	5	6
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	3 (100.0%)	5 (100.0%)	6 (100.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*				
			Cohort 1 (N = 6)	Cohort 2 (N = 6)	Cohort 3 (N = 6)	Cohort 4 (N = 6)	Cohort 5 (N = 6)
Has subject completed Suicide since last visit?	Day 8	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
	Early Termination	N	0	0	0	0	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

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Table 14.3.5.5 - Columbia-Suicide Severity Rating Scale (C-SSRS)

C-SSRS Questions	Visit	Results	Treatment Group*			
			Cohort 6 (N = 6)	Cohort 7 (N = 6)	Cohort 8 (N = 6)	Placebo (N = 16)
Has subject completed Suicide since last visit?	Day 8	N	6	0	5	4
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	6 (100.0%)	0 ( 0.0%)	5 (100.0%)	4 (100.0%)
	Early Termination	N	0	3	1	0
		Yes	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)
		No	0 ( 0.0%)	3 (100.0%)	1 (100.0%)	0 ( 0.0%)

\* Full term of treatment group is listed as below.

Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);  
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day)  
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);  
And Placebo (all cohorts combined).

Program: 14.3.5.5.cssrs.sas

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