16.2.7 Adverse Event Listings

Data Listing 16.2.7 - Adverse Events

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

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Treatment Group*	Patient ID	System Orgran Class /Preferred Term	Serious Event	Severity	Causality	Outcome	Action	Start Date	End Date
Cohort 1	01S0002	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	23JAN2020	28JAN2020
	01S0003	Gastrointestinal Disorders/Diarrhoea	NO	MILD	UNLIKELY	RECOVERED /RESOLVED	NOT APPLICABLE	22JAN2020	22JAN2020
		Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	24JAN2020	29JAN2020
	01S0004	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	24JAN2020	29JAN2020
	01S0005	Infections And Infestations/Upper Respiratory Tract Infection	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	25JAN2020	30JAN2020

* Full term of treatment group is listed as below.
Cohort 1: LB-102 50 mg QD (1 day); Cohort 2: LB-102 10 mg QD (1 day); Cohort 3: LB-102 100 mg QD (1 day);
Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day
Cohort 7: LB-102 100 mg BID (6 days) + QD (1 day); Cohort 8: LB-102 75 mg BID (6 days) + QD (1 day);
And Placebo (all cohorts combined).

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Cohort 2	01S0030	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	06FEB2020	11FEB2020
	01S0042	Gastrointestinal Disorders/Abdominal Pain	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	09FEB2020	11FEB2020
Cohort 3	01S0063	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	20FEB2020	25FEB2020
		Skin And Subcutaneous Tissue Disorders/Urticaria	NO	MILD	POSSIBLY	RECOVERED /RESOLVED	NOT APPLICABLE	18FEB2020	18FEB2020

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Cohort 4: LB-102 200 mg 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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Cohort 3	01S0071	Infections And Infestations/Upper Respiratory Tract Infection	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	21FEB2020	27FEB2020
	01S0073	Gastrointestinal Disorders/Nausea	NO	MILD	PROBABLY	RECOVERED /RESOLVED	NOT APPLICABLE	18FEB2020	18FEB2020
Cohort 4	01S0116	Investigations/Electrocardiogram Qt Prolonged	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	DOSE NOT CHANGED	03MAR2020	03MAR2020
	01S0119	Cardiac Disorders/Palpitations	NO	MILD	UNLIKELY	RECOVERED /RESOLVED	NOT APPLICABLE	03MAR2020	03MAR2020

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Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day
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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Cohort 4	01S0119	Nervous System Disorders/Dystonia	NO	MODERATE	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	03MAR2020	03MAR2020
	01S0120	Gastrointestinal Disorders/Gastrooesophageal Reflux Disease	NO	MILD	POSSIBLY	RECOVERED /RESOLVED	NOT APPLICABLE	03MAR2020	03MAR2020
		Gastrointestinal Disorders/Nausea	NO	MILD	POSSIBLY	RECOVERED /RESOLVED	NOT APPLICABLE	03MAR2020	03MAR2020
		Nervous System Disorders/Headache	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	10MAR2020	10MAR2020
		Psychiatric Disorders/Insomnia	NO	MILD	PROBABLY	RECOVERED /RESOLVED	NOT APPLICABLE	03MAR2020	04MAR2020

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Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day
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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Cohort 4	01S0120	Respiratory, Thoracic And Mediastinal Disorders/Oropharyngeal Pain	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	10MAR2020	14MAR2020
Cohort 5	01S0157	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	20APR2020	02MAY2020
Cohort 6	01S2050	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	20MAY2020	26MAY2020
	01S2053	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	20MAY2020	26MAY2020

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Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day
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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Cohort 7	01S2066	Gastrointestinal Disorders/Dry Mouth	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	04JUN2020	06JUN2020
		Nervous System Disorders/Dystonia	NO	MODERATE	DEFINITELY	RECOVERED /RESOLVED	DRUG WITHDRAWN	04JUN2020	04JUN2020
		Nervous System Disorders/Somnolence	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	04JUN2020	05JUN2020
	01S2069	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	04JUN2020	12JUN2020
	01S2079	Gastrointestinal Disorders/Nausea	NO	MODERATE	PROBABLY	RECOVERED /RESOLVED	NOT APPLICABLE	04JUN2020	04JUN2020

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Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day
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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Cohort 7	01S2079	Gastrointestinal Disorders/Vomiting	NO	MILD	POSSIBLY	RECOVERED /RESOLVED	NOT APPLICABLE	04JUN2020	04JUN2020
		Nervous System Disorders/Dystonia	NO	MODERATE	DEFINITELY	RECOVERED /RESOLVED	NOT APPLICABLE	04JUN2020	04JUN2020
Cohort 8	01S2080	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	DOSE NOT CHANGED	26JUN2020	07JUL2020
	01S2092	Nervous System Disorders/Dystonia	NO	MODERATE	DEFINITELY	RECOVERED /RESOLVED	DRUG WITHDRAWN	25JUN2020	25JUN2020
		Nervous System Disorders/Migraine	NO	MODERATE	POSSIBLY	RECOVERED /RESOLVED	DRUG WITHDRAWN	24JUN2020	25JUN2020

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Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day
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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Cohort 8	01S2093	Gastrointestinal Disorders/Nausea	NO	MILD	PROBABLY	RECOVERED /RESOLVED	DOSE NOT CHANGED	23JUN2020	28JUN2020
		Nervous System Disorders/Dizziness	NO	MILD	PROBABLY	RECOVERED /RESOLVED	DOSE NOT CHANGED	23JUN2020	29JUN2020
		Nervous System Disorders/Somnolence	NO	MILD	PROBABLY	RECOVERED /RESOLVED	DOSE NOT CHANGED	23JUN2020	29JUN2020
	01S2094	Investigations/Blood Prolactin Increased	NO	MILD	DEFINITELY	RECOVERED /RESOLVED	DOSE NOT CHANGED	26JUN2020	10JUL2020
	01S2102	Musculoskeletal And Connective Tissue Disorders/Back Pain	NO	MILD	UNRELATED	RECOVERED /RESOLVED	DOSE NOT CHANGED	25JUN2020	27JUN2020

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Cohort 4: LB-102 200 mg 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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Cohort 8	01S2102	Psychiatric Disorders/Insomnia	NO	MILD	POSSIBLY	RECOVERED /RESOLVED	DOSE NOT CHANGED	24JUN2020	28JUN2020
Placebo	01S0068	Nervous System Disorders/Headache	NO	MILD	PROBABLY	RECOVERED /RESOLVED	NOT APPLICABLE	18FEB2020	20FEB2020
	01S0169	Musculoskeletal And Connective Tissue Disorders/Back Pain	NO	MILD	UNRELATED	RECOVERED /RESOLVED	NOT APPLICABLE	19APR2020	25APR2020
	01S2047	Nervous System Disorders/Dizziness	NO	MILD	UNRELATED	RECOVERED /RESOLVED	DOSE NOT CHANGED	12MAY2020	12MAY2020
	01S2082	Gastrointestinal Disorders/Abdominal Pain	NO	MILD	UNRELATED	RECOVERED /RESOLVED	DOSE NOT CHANGED	25JUN2020	25JUN2020

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Cohort 4: LB-102 200 mg 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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Placebo	01S2095	Injury, Poisoning And Procedural Complications/Arthropod Bite	NO	MILD	UNRELATED	RECOVERED /RESOLVED	DOSE NOT CHANGED	29JUN2020	01JUL2020

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Cohort 4: LB-102 200 mg QD (1 day); Cohort 5: LB-102 150 mg QD (1 day); Cohort 6: LB-102 50 mg BID (6 days) + QD (1 day
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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