



To: Medpace Clinical Pharmacology Unit

From: Zachary Prenskey, CEO - LB Pharmaceuticals

Date: November 26, 2019

RE: Clarification Memo #1

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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The intent of this protocol clarification memo is to provide clarification for the LB-102-001 protocol (Original Protocol, 21 October 2019). All items listed below will be incorporated into the next amendment, if an amendment is necessary.

The below section is to clarify the procedure for reporting pregnancies of a female subject or female partner of a male subject.

#### **Reporting Pregnancies**

If a female subject or the female partner of a male subject becomes pregnant during the course of the study, or within 30 days after the last dose of study drug/placebo, the Investigator must report the pregnancy to Target Health LLC. within 24 hours of being notified. Target Health LLC. will then forward the Exposure in Utero form to the Investigator for completion. The Investigator must obtain consent to collect pregnancy information from the female subject or female partner of a male subject (including the outcome of the pregnancy and any SAEs, if applicable).

A subject becoming pregnant while on study drug will immediately be withdrawn from further dosing but will continue to be followed throughout the duration of the study.

The subject or partner should be followed by the Investigator until completion of the pregnancy, whenever possible. If the pregnancy ends for any reason before the anticipated date, the Investigator should notify Target Health LLC. At the completion of the pregnancy, the Investigator will document the outcome of the pregnancy. If the outcome of the pregnancy meets the criteria for immediate classification as an SAE (i.e., postpartum complication, spontaneous abortion, stillbirth, neonatal death, or congenital anomaly), the Investigator should follow the procedures for reporting an SAE

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Zachary Prenskey, CEO

  
Signature

  
Date