



LB Pharmaceuticals Announces the Initiation of Patient Dosing in a First-in-Human Phase 1 Study of LB-102, a Novel Benzamide for the Treatment of Schizophrenia

New York, NY (January 22nd, 2020) – LB Pharmaceuticals, Inc., (“LB”, or the “Company”) a biotechnology company focused on developing novel and improved versions of successful CNS treatments, announced today the administration of the first dose of LB-102 in a Phase 1 clinical trial. LB-102 is a novel benzamide designed to be an improved version of amisulpride, a drug successfully used in Europe but unavailable in the United States. The ongoing study aims to evaluate the safety, tolerability, and pharmacokinetics/pharmacodynamics of LB-102 in healthy volunteers.

LB-102 was designed to mimic amisulpride’s binding affinity to the D₂/D₃ and 5HT₇ receptors while improving brain permeability. Amisulpride is approved for the treatment of schizophrenia and is widely prescribed in over 50 countries, including the EU. In *in vitro* and *in vivo* preclinical assays, LB-102’s biophysicochemical properties, including PK, receptor binding, and behavioral studies, were equivalent or superior to amisulpride’s.

“The preclinical activity profile of LB-102 suggests that it has the potential to build upon the excellent efficacy and safety profile observed in the clinical use of amisulpride for over 20 years”, stated Zachary Prensky, President and CEO. “We believe that, if approved, LB-102 would make for a useful addition to the toolbox of treatments available to psychiatrists for the treatment of schizophrenia. Schizophrenia affects approximately 3 million Americans and in many patients, approved antipsychotics offer only modest efficacy and significant side effects.”

About LB-102

LB-102 (*N*-methyl amisulpride) was designed to be an improved version of the benzamide antipsychotic amisulpride. *In vitro* binding of LB-102 to important CNS receptors (adrenergic, dopaminergic, histaminergic, muscarinic, and serotonergic) has been measured and LB-102 bound most strongly to the dopamine D₂ and D₃ receptors, having low single digit nM K_is, and also showing some affinity for the 5HT₇ receptor (K_i of 32 nM). Also *in vitro*, the ability of LB-102 to passively diffuse across a neutral membrane was compared to amisulpride which showed that LB-102 was better able to penetrate said membrane ~200 fold. In three *in vivo* models of schizophrenia, LB-102 showed efficacy comparable or superior to amisulpride. The Company has been issued U.S. patents covering the composition of matter and potential uses of LB-102.

About LB Pharmaceuticals

LB is a development stage CNS-focused life science company devoted to commercializing novel and improved versions of successful CNS treatments used extensively overseas but never developed or approved in the United States. Our approach is to create a research-focused organization dedicated to generating novel intellectual property around improved versions of these former commercially successful drugs.

More information about LB-102 and the Company may be found on our corporate website, located at www.LBPharma.us

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