LB Pharmaceuticals Inc Announces Results of LB-102 Phase 1 First-in-Human Clinical Study

- *Phase 1 clinical trial evaluated multiple doses of LB-102 (N-*methyl amisulpride) *in 64 healthy adults ages 18-55 years*
- *LB-102 was safe and well-tolerated and displayed dose linear PK*
- *Phase 2 clinical study in schizophrenia patients planned for mid- 2021; retains Mizuho Securities as exclusive financial advisor*

New York, NY (Sept 14th, 2020) – LB Pharmaceuticals Inc, ("LB", or the "Company"), a biotechnology company focused on developing and commercializing novel and improved versions of successful CNS treatments, today announced the results of a Phase 1 clinical study of LB-102 (NCT04187560), a novel derivative of amisulpride designed to treat schizophrenia. Data from this study were presented at the 33rd annual meeting of the European College of Neuropsychopharmacology (ECNP), which is being held virtually. A copy of the Company's poster can be viewed online at http://lbpharma.us/presentations/

This was a combined single ascending dose (SAD)/multiple ascending dose (MAD) study with safety as the primary endpoint and PK as a secondary endpoint. Sixty-four healthy volunteers were dosed orally with LB-102 at doses ranging from 10 mg to 200 mg. Top line results of this study include:

- LB-102 was well-tolerated up to 150 mg/day
- Adverse events were consistent with dopamine antagonists and included transient increases in QT interval and prolactin levels, though these did not result in clinical observations
- Dosing in the 100 mg BID cohort in the MAD was discontinued due to the occurrence of extrapyramidal symptoms (EPS), a biomarker typically associated with >80% dopamine receptor occupancy
- Plasma concentrations of LB-102 were ~2.5 times greater than published values of amisulpride at the same dose, suggesting LB-102 could be dosed substantially lower than amisulpride

"LB-102 was designed to be a more potent version of amisulpride and the EPS and PK data from this study provide, potentially, an early proof of concept" commented Dr. Andrew Vaino, Chief Scientific Officer of LB.

"The data from our Phase 1 study suggest that we are on the right track. In LB-102 we are seeing the first signs of a novel, patented, benzamide that appear to mimic the properties of amisulpride at lower doses", stated Zachary Prensky, President and CEO. "We're looking forward to following up with a PET study later this year to directly measure dopamine receptor occupancy in a clinical study. Data from this study that will help us determine dose levels for

the Phase 2 clinical study in schizophrenia patients that we're planning for 2021. All in all, we're pleased with how this study went, and are excited to be turning the page towards the next chapter of clinical development", added Mr. Prensky.

"With a successful Phase 1 study behind us, I am looking forward to working with our senior clinical partners, key stakeholders, and the team at Mizuho Securities to put in place the financing necessary to move LB-102 into mid-stage clinical development", added Marc Panoff, Chief Financial Officer of LB.

About LB-102

LB-102, or *N*-methyl amisulpride, is a patented benzamide designed to be an improved version of amisulpride, a dopamine/5-HT7 antagonist successfully used to treat schizophrenia in Europe for decades. LB-102 was designed to improve on amisulpride's low permeability across the blood brain barrier. LB-102 has the potential to offer schizophrenia patients the benefits of amisulpride at a lower dose than amisulpride. A first-in-patient, placebo-controlled, Phase 2 study designed to test the safety and efficacy of LB-102 in the treatment of schizophrenia is planned for mid-2021.

About LB Pharmaceuticals

LB is a clinical stage CNS-focused life science company devoted to commercializing novel and improved versions of successful CNS treatments used extensively overseas but never approved in the United States. LB-102, or *N*-methyl amisulpride, is the Company's lead clinical asset. LB was founded in 2015 and is based in New York City.

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