Lobe Sciences Ltd. Announces Regulatory and Clinical Development Plans For 2022 and Early 2023

Vancouver, British Columbia--(Newsfile Corp. - July 7, 2022) - Lobe Sciences Ltd. (CSE: LOBE) (OTCQB: LOBED) ("Lobe" or the "Company"), a Canadian Biotechnology company committed to discovering and developing psychedelic derived medicines today announced it has developed its initial Phase 1 study plan intended to demonstrate the safety and appropriate dosing range for its proprietary new chemical entity; L-130. It is also announcing the acquisition of a second new chemical entity, L-131, which is expected to enter preclinical toxicity trials later this year or early in 2023.

Philip Young, CEO of Lobe Sciences stated, "L-130 and L-131 are unique synthetic analogues of psilocin, the active metabolite of natural psilocybin, a substance extracted from a species of psychedelic mushroom. We have designed a regulatory development strategy to support the registration of these new chemical entities with the U.S. Food and Drug Administration (FDA). Our initial focus for our clinical program is to treat neurologic disorders, such as severe anxiety and we are in the final stages of selecting a contract research organization to support these studies."

We expect to submit a Pre-IND meeting request with the FDA in the third quarter of this year. After receiving the FDA response to our Pre-IND questions, we will file our investigational new drug application (IND) to enable us to move forward with our initial clinical study later this year or early in 2023.

Our initial Phase 1 study will evaluate the safety of L-130 in healthy volunteers in a single ascending dose trial. Following this, a second Phase 1 trial will evaluate longer term use of the drug candidate in a multiple ascending dose study (MAD). Once an appropriate dosing level is determined to have no hallucinatory effect, we will conduct a third and final safety study in patients evaluating both pharmacokinetics and preliminary efficacy at the selected dose. This Phase Ib MAD trial will also seek to confirm the synergistic effects seen in preclinical studies when combinations with N-acetyl cysteine (NAC) were administered with a similar psychedelic compound. Lobe has filed a patent protecting the use of NAC in combination with various psychedelic derived compounds.

Lobe's approach is focused on providing a therapeutic that employs sub-psychedelic dose levels to treat patients at home or in their physician's office and avoiding long stays associated with other treatment modalities. Delivering a non-hallucinatory dose of L-130 over several days will enable patients and their doctors the opportunity to maintain their normal routine while receiving treatment.

L-131 will enter preclinical rodent studies in late 2022 or early 2023 to evaluate its safety and pharmacokinetics. The initial trial will be a standard 28-day preclinical safety study to enable human Phase 1 trials planned later in 2023.

About Lobe Sciences Ltd.

Lobe Sciences is a life sciences company focused on psychedelic medicines. The Company, through collaborations with industry-leading partners, is engaged in drug research and development using psychedelic compounds and the development of innovative devices and delivery mechanisms to improve mental health and wellness.

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