Tryp Therapeutics Submits IND Application for Phase 2a Clinical Trial in Eating Disorders

SAN DIEGO – Sept. 22, 2021 - Tryp Therapeutics (CSE:TRYP; OTCQB:TRYPF) ("Tryp"), a pharmaceutical company focused on developing psilocybin-based compounds for diseases with unmet medical needs, announced today that it has submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") to evaluate its clinical candidate, TRP-8802, in a Phase 2a study for the treatment of patients with eating disorders.

The trial is being conducted with Jennifer Miller, M.D., from the University of Florida and will evaluate the Company's oral formulation of synthetic psilocybin, TRP-8802, in combination with psychotherapy. The IND application includes details regarding the safety of the drug product, the protocol for the study, the informed consent information for patients, and other information. Tryp expects to initiate the Phase 2a study in Q4 of this year subject to a favorable review of the IND by the FDA.

"The submission of this IND represents hundreds of hours of preparation, design, and coordination as we pursue a leading-edge treatment of psilocybin with psychotherapy," commented Dr. Miller. "I have been thoroughly impressed with the team at Tryp and enjoy our shared commitment to exploring new treatments for our patients who have so few existing therapies available to them."

The Phase 2a clinical trial is expected to enroll ten patients with various overeating disorders including binge eating disorder, hypothalamic obesity, and Prader-Willi Syndrome. The administration of psilocybin is expected to increase neuroplasticity and to help create healthy neural patterns related to hunger and eating. Patients will meet with psychotherapists who have been trained by Fluence for two sessions prior to the administration of TRP-8802, which will take place in two drug-dosing sessions. Integration sessions with the psychotherapists will be conducted after the administration of the drug.

"This IND submission marks the most important milestone the Company has achieved to date and will be critical in identifying patient responses to the active ingredient, consistent with that of our proprietary drug candidate, TRP-8803, that will be used in Phase 2b trials and beyond," commented Greg McKee, Chairman and Chief Executive Officer of Tryp. "This is the first of several IND filings we expect to make in the coming months in support of our work to address various chronic pain and eating disorder indications, and we are eager to begin enrolling our first patients in multiple Phase 2a trials later this year."

About Tryp Therapeutics

Tryp Therapeutics is a pharmaceutical company focused on developing psilocybin-based compounds for the treatment of diseases with unmet medical needs through accelerated regulatory pathways. Tryp's Psilocybin-For-Neuropsychiatric Disorders (PFN™) program is focused on the development of synthetic psilocybin as a new class of drug for the treatment of chronic pain and other indications. The Company has announced upcoming Phase 2a clinical trials with the University of Michigan and the University of Florida to evaluate its drug products for fibromyalgia and overeating disorders, respectively. Tryp is also developing a proprietary psilocybin-based product, TRP-8803, that uses a novel formulation and method of delivery to improve the patient experience. For more information, please visit www.tryptherapeutics.com.

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