

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

San Diego, California--(Newsfile Corp. - November 2, 2021) - [Tryp Therapeutics](#) (CSE: TRYP) (OTCQB: TRYPF) ("**Tryp**" or the "**Company**"), 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 clinical trial that investigates safety and preliminary effectiveness of psilocybin-assisted therapy among patients with fibromyalgia in collaboration with the University of Michigan.

The trial is being conducted with Kevin Boehnke, Ph.D. from the University of Michigan and will evaluate the Company's oral formulation of synthetic psilocybin, TRP-8802, in combination with psychotherapy. The application includes details regarding the trial protocol and safety information. Tryp expects to initiate the Phase 2a study in 2022 subject to a favorable review of the IND by the FDA.

"Many fibromyalgia patients find insufficient relief from the currently available, FDA-approved treatments for the disease due to their limited efficacy and significant side effects," commented Dr. Boehnke. "We have an opportunity with Tryp to conduct a Phase 2a study that evaluates the safety and clinical utility of psilocybin for fibromyalgia as we target the origins of the disease rather than simply treating patient symptoms."

The Phase 2a open label clinical trial is expected to enroll 20 fibromyalgia patients and includes a variety of exploratory endpoints given the high prevalence of co-morbidities such as poor sleep quality, depression, anxiety, and other conditions. The administration of psilocybin is expected to increase neuroplasticity and to address disrupted neural connections that are typical of fibromyalgia and other nociplastic pain indications. Patients will meet with psychotherapists before, during, and after the dosing of TRP-8802.

"We have been working diligently to complete this IND submission and are eager to initiate what will be one of the first evaluations of psilocybin to treat fibromyalgia in a Phase 2 study," said Greg McKee, Chairman and Chief Executive Officer of Tryp. "Through our close collaboration with Dr. Boehnke and other experts in the space, we have an appreciation of the limitations of current treatments for this disease and a determination to develop a more effective therapy for the millions of patients suffering from fibromyalgia."

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 route of administration to improve the patient experience. For more information, please visit www.trypterapeutics.com.

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