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News

Tryp Therapeutics Announces Plans for Phase 2a Clinical Trial for Fibromyalgia with the University of Michigan

The study is expected to be the world's first Phase 2a clinical trial evaluating the efficacy of psilocybin and psychotherapy to treat fibromyalgia

San Diego, California – July 21, 2021 - [Tryp Therapeutics](#) (CSE:TRYP; OTCQB:TRYPF) (“Tryp”), a pharmaceutical company focused on developing psilocybin-based compounds for diseases with unmet medical needs through accelerated regulatory pathways, announced today its plans to conduct a Phase 2a clinical trial with the [Chronic Pain & Fatigue Research Center](#) in the Department of Anesthesiology at the University of Michigan Medical School.

The open-label Phase 2a clinical trial will evaluate the efficacy of TRYP-8802, an oral formulation of synthetic psilocybin, in tandem with psychotherapy for treating fibromyalgia. The treatment is designed to target nociplastic pain originating in the central nervous system through the neuroplasticity benefits of psilocybin. The Principal Investigator for the trial will be Kevin Boehnke, Ph.D., Research Investigator, University of Michigan Department of Anesthesiology. Tryp will seek to identify a response in patients to the treatment to inform the design of a Phase 2b clinical trial for fibromyalgia that will use the company’s proprietary, psilocybin-based drug product, TRP-8803, that includes a novel formulation and unique method of delivery.

“Existing treatment options for fibromyalgia are often ineffective and show significant side effects,” said Daniel Clauw, M.D., Director of the Chronic Pain & Fatigue Research Center. “Kevin Boehnke and I are excited to be working with the team at Tryp Therapeutics, who have shown exceptional scientific rigor in their approach to evaluate a new treatment paradigm for the millions of patients suffering from fibromyalgia and other pain-related indications.”

Fibromyalgia is a disease of the central nervous system that is estimated to affect as much as 2% to 8% of the population. The disease is characterized by widespread pain commonly accompanied by fatigue, memory problems, and sleep disturbances. With available treatment options often proving ineffective, nearly 30% of fibromyalgia patients alarmingly resort to opioid-based medications in an attempt to address symptoms of pain stemming from the disease. Tryp expects to submit the Investigational New Drug (IND) application to the FDA for the Phase 2a clinical trial in 3Q 2021.

“We are thrilled to collaborate with such forward-looking clinicians and scientists to develop additional treatment options for fibromyalgia,” commented Jim Gilligan, Ph.D., President and Chief Science Officer at Tryp Therapeutics. “The Chronic Pain & Fatigue Research Center at the University of Michigan brings incomparable experience with evaluating treatments for fibromyalgia and other chronic pain indications, and there is nothing more important to our collective team than creating therapies that will address the daily distress of these patients.”

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 eating disorder 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 eating 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.

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Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by Tryp as of the date of this news release, are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information, including but not limited to the factors described in greater detail in the "Risk Factors" section of Tryp's final prospectus available at www.sedar.com. These factors are not intended to represent a complete list of the factors that could affect Tryp; however, these factors should be considered carefully. There can be no assurance that such estimates and assumptions will prove to be correct. The forward-looking statements contained in this news release are made as of the date of this news release, and Tryp expressly disclaims any obligation to update or alter statements containing any forward-looking information, or the factors or assumptions underlying them, whether as a result of new information, future events or otherwise, except as required by law.

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