

Tryp Therapeutics Receives Confirmation from FDA to Proceed with Phase 2a Study in Fibromyalgia

SAN DIEGO, Dec. 2, 2021 /CNW/ -- [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 received confirmation from the U.S. Food and Drug Administration ("FDA") that its review of Tryp's Investigational New Drug ("IND") application is complete and that the Company may proceed with its clinical study in fibromyalgia.

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. Tryp expects to initiate the Phase 2a study in 2022.

"The upcoming Phase 2a study with the University of Michigan for fibromyalgia represents a significant milestone for Tryp's clinical programs," commented Greg McKee, Chairman and CEO of Tryp Therapeutics. "We are eager to begin enrolling patients in the study next year considering the significant, unmet needs of fibromyalgia patients."

The Phase 2a open label clinical trial will enroll 20 fibromyalgia patients and includes a variety of secondary and exploratory endpoints given the high prevalence of co-morbidities such as poor sleep quality, depression, anxiety, and other conditions in patients suffering from fibromyalgia. The administration of psilocybin is expected to increase neuroplasticity and to address disrupted neural connections that have been reported for nociplastic pain indications. The clinical trial will be one of the first evaluations of synthetic psilocybin for fibromyalgia in a Phase 2 study.

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.tryptherapeutics.com.

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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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