PharmaDrug Announces Clinical Research Collaboration with The Johns Hopkins University to Evaluate DMT in a Comparative Clinical Study

Toronto, Ontario--(Newsfile Corp. - August 25, 2021) - PharmaDrug Inc. (CSE: PHRX) (OTC Pink: LMLLF) ("**PharmaDrug**" or the "**Company**"), a specialty pharmaceutical company focused on the research, development and commercialization of controlled-substances and natural medicines such as psychedelics, cannabis and naturally-derived approved drugs, is pleased to announce that the Company has entered into a Clinical Trial Agreement with The Johns Hopkins University (JHU) to conduct a clinical study comparing acute and enduring psychological and neural effects of N,N-Dimethyltryptamine (DMT) and an undisclosed, potently active comparator molecule. The principal investigator, Dr. Frederick S. Barrett, PhD, Associate Professor of Psychiatry and Behavioral Sciences, will be supported by Co-investigators Dr. Sandeep Nayak and Dr. Roland Griffiths; all from the JHU Center for Psychedelic and Consciousness Research.

The potential of psychedelic drugs to treat various neuropsychiatric indications is currently being explored in several human clinical trials. The dramatic mind-altering effects of these drugs is well known, and as such, a study volunteer's expectancy may contribute to clinical outcomes. Such effects are considered classic study confounds and can lead to misinterpretation of efficacy signals. For example, this phenomenon was recently noted in a large, placebo-controlled study of LSD which found that those receiving LSD or placebo showed significant improvements in mood, anxiety, creativity and energy[1]. To address this common study design limitation and to assess the neuropsychiatric impact of DMT more fully, the Company has sponsored the submission of an Investigational New Drug ("IND") application to the U.S Food and Drug Administration ("FDA") which aims to compare the effects of DMT with another potently psychotropic drug.

The first part of the planned study will examine dose effects of DMT and the other test article. During the second part of the study, healthy subjects will be exposed to a maximum tolerated dose of each drug (as defined in part 1 of the study). During both parts of the study, investigators will carefully characterize any acute and persisting subjective, affective, cognitive, and neural dose-dependent effects for both drugs being evaluated. Much debate exists around the relative potential benefits of micro vs macro-doses for psychedelic compounds. Using a highly controlled approach, the currently planned clinical trial will go some way to answering this important question. Employing an extensive battery of psychological assessment tools, coupled with state-of-the-art functional MRI and EEG the JHU researchers endeavour to develop a more fulsome understanding of how DMT acts in the brain of healthy volunteers; with the ultimate goal of being able to apply this knowledge in tailoring the treatment of serious neuropsychiatric conditions.

This clinical research collaboration builds upon PharmaDrug's existing strategy of focusing on establishing a better understanding of the basic mechanisms by which DMT exerts its effects in the brain and elsewhere in the body. By supporting world class talent with distinct expertise in early discovery and clinical use the Company will be optimally positioned to identify novel applications for DMT and unlock its full therapeutic potential. The Company intends to become a leader in advancing DMT as a prescription pharmaceutical, and as previously reported, is the first organization to receive orphan drug designation by the U.S. FDA for DMT in the prevention of ischemia-reperfusion injury in patients undergoing solid organ transplantation, which includes the liver, kidney, heart, and lungs. As a further example of PharmaDrug's commitment to DMT development, the Company recently entered into a sponsored research agreement with the Terasaki Institute to evaluate the potential of novel DMT delivery systems for the treatment of primary open angle glaucoma, one of the leading causes of vision loss worldwide.

Daniel Cohen, CEO of PharmaDrug commented: "We are excited to collaborate and support Dr. Frederick Barrett to better understand DMT and its potential. The JHU Center for Psychedelic and Consciousness Research is a global leader in psychedelics clinical research, and we are very grateful to partner with them to achieve our objectives in expanding our pharmaceutical product pipeline for novel uses and delivery forms of DMT to treat unmet medical needs."

Under the terms of the agreement, the Company has an exclusive option to obtain worldwide, royalty-bearing commercialization license to all rights, title, and interest that JHU may have or obtain in any invention that results from the clinical study.

About PharmaDrug Inc.

PharmaDrug is a specialty pharmaceutical company focused on the research, development and commercialization of controlled-substances and natural medicines such as psychedelics, cannabis and naturally-derived approved drugs. The Company owns 80% of Pharmadrug Production GmbH, a German medical cannabis distributor, with a Schedule I European Union narcotics license and German EuGMP certification allowing for the importation and distribution of medical cannabis to pharmacies in Germany and throughout the EU. The Company also owns 100% of Super Smart, a Dutch company building a modern adult use psychedelic retail business with an elevated and educational focus. PharmaDrug recently acquired Sairiyo Therapeutics, a biotech company that specializes in researching and reformulating established natural medicines with a goal of bringing them through regulatory and research driven clinical trials.

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References:

1) Szigeti B, Kartner L, Blemings A, Rosas F, Feilding A, Nutt DJ, Carhart-Harris RL, Erritzoe D. Self-blinding citizen science to explore psychedelic microdosing. Elife. 2021 Mar 2;10:e62878. doi: 10.7554/eLife.62878. PMID: 33648632; PMCID: PMC7925122.