CISION

Wake Network Receives Approval for Phase 2b Psilocybin Microdosing Trial



TORONTO, Sept. 23, 2021 /CNW/ - Wake Network, Inc. ("Wake" or the "Company"), a global leader in naturally-derived psilocybin production and the developer of genomics-based integration therapies, is pleased to announce the Company has received a Certificate of Drug Registration from the Jamaican Ministry of Health & Wellness for its naturally derived psilocybin microdose formulation, PSIL428.

This is a critical milestone for Wake to run its own clinical trials by creating safety and efficacy data for its legal, proprietary psilocybin drug product, PSIL428. PSIL428 is one of the first psilocybin microdose formulations produced worldwide, which is derived from natural fungi material. This will allow the Company to address the growing demand for mushroom-based psilocybin microdosing used for therapeutic purposes. It also adds a layer of control that is committed to quality, consistency, and reliability from dose to dose.

PSIL428 and the data on its safety and efficacy created through Wake's clinical trials will be available to clinics, treatment centres, and academic centres worldwide. As one of the only legal natural psilocybin drug forms in the world, it can be imported by request for patient use in any country with a special access program in place.

"We are very excited about our natural psilocybin microdose formulation being registered as a research drug by the Jamaican Ministry of Health & Wellness", said Olga Chernoloz, Chief Scientific Officer of Wake, "It means that Wake and the clinical communities that are interested in investigating the clinical potential of psilocybin will now have access to this product. PSIL428's natural origin is an added bonus for those considering the potential benefits of full-spectrum formulations."

PSIL 428 will be used in Wake's double-blind, randomized, placebo-controlled clinical trial assessing the effects of microdosing on anxiety and depression. The study is fully approved and registered with the National Institutes of Health, ClinicalTrials.gov Identifier: NCT04989972

ABOUT WAKE NETWORK, INC.

Wake Network, Inc. is a fungi bioscience company focused on advancing, through research, the field of psychedelic and fungi-based therapeutics. To address the growing need for psychedelic-assisted mental health support in medicine and society at large, Wake has partnered with academics, governments and best-in-class mycologists around the world. Wake is currently developing fungus-derived psilocybin and is making advancements in the engineering of novel psychedelic biologics, while working on proving out their safety through proprietary genetics-based integration therapies.

https://www.newswire.ca/news-releases/wake-network-inc-receives-certificate-of-drug-registration-for-microdose-formulation-in-jamaica-895428231.html