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U.S. FDA Clears MYCO-001 for Multi-Site Government Funded Trial in Smoking Cessation

DENVER, June 17, 2022 (GLOBE NEWSWIRE) -- Mydecine Innovations Group (NEO: MYCO) (OTC: MYCOF) (FSE: 0NFA) (“Mydecine” or the “Company”), a biotechnology aiming to transform the treatment of mental health and addiction disorders, today announced that the U.S. Food and Drug Administration (FDA) has cleared MYCO-001 in a recent Investigational New Drug (IND) application, marking the first clearance of the Company’s drug product.

The Investigator Initiated trial is funded by a near $4 million grant from the National Institutes of Health, making this the first time in 50 years the U.S. government has funded a study evaluating a psychedelic compound for therapeutic use. The randomized trial aims to determine if psilocybin increases smoking abstinence compared to a placebo, both paired with cognitive-behavioral therapy (CBT).

“Mydecine looks forward to supplying the placebo and our MYCO-001 drug product for this study,” said Mydecine CEO Josh Bartch. “The FDA clearance is encouraging as we prepare to submit the IND for our Industry Sponsored Phase 2b trial using the same drug products.”

The recently cleared grant-funded trial is led by Principal Investigator (PI)Dr. Matthew Johnson, Ph.D., Professor of Psychiatry and Behavioral Sciences at Johns Hopkins University. Dr. Johnson is a globally recognized leader who has researched and published extensively on the science of psychedelics for more than 16 years.

Other PI’s include Michael P. Bogenschutz, M.D., Director of the New York University (NYU) Langone Center for Psychedelic Medicine and Professor, Department of Psychiatry at NYU Grossman School of Medicine, as well as Peter Hendricks, Ph.D., professor in the Department of Health Behavior at the University of Alabama School of Public Health and a site principal investigator.

The grant-funded research and Mydecine's Phase 2b study expand on previous research led by Dr. Johnson and his team. A study conducted in 2014 assessed the efficacy of psilocybin, in combination with CBT, as a treatment for tobacco addiction. At six months, 80 percent of individuals were biologically proven to be smoking abstinent.

“Supportive clinical trial results have generated interest in studying psychedelic-assisted therapy across multiple indications. We look forward to supplying psilocybin to help advance the exploration of research in this field,” said Mydecine Sr. Director of Clinical and Regulatory Affairs, Jessica Riggleman.

About Mydecine Innovations Group

Mydecine Innovations GroupTM (NEO:MYCO) (OTC:MYCOF) (FSE:0NFA) is a biotechnology company developing innovative first- and-second-generation novel therapeutics for the treatment of mental health and addiction using world-class technology and drug development infrastructure. Mydecine was founded in 2020 to address a significant unmet need and lack of innovation in the mental health and therapeutic treatment environments. Our global team is dedicated to efficiently developing new therapeutics to treat PTSD, depression, anxiety, addiction and other mental health disorders. The Mydecine business model combines clinical trials and data outcome, technology, and scientific and regulatory expertise with a focus on psychedelic therapy, as well as other novel, non-psychedelic molecules with therapeutic potential. By collaborating with some of the world's foremost authorities, Mydecine aims to responsibly fast-track the development of new medicines to provide patients suffering from mental health disorders with safe and more effective treatment options. Mydecine Innovations Group is headquartered in Denver, Colorado, USA, with international offices in Leiden, Netherlands.

Learn more at: https://www.mydecine.com and follow us on Twitter, LinkedIn, YouTube and Instagram.

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For further information about Mydecine Innovations Group, Inc., please visit the Company's profile on SEDAR at www.sedar.com or visit the Company's website at www.mydecine.com.

This news release contains forward-looking information within the meaning of Canadian securities laws regarding the Company and its business, which relate to future events or future performance and reflect management's current expectations and assumptions. Often but not always, forward-looking information can be identified by the use of words such as "expect", "intends", "anticipated", "believes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would" or "will" be taken, occur or be achieved. Such forward-looking statements reflect management's current beliefs and are based on assumptions made by and information currently available to the Company. Readers are cautioned that these forward-looking statements are neither promises nor guarantees, and are subject to risks and uncertainties that may cause future results to differ materially from those expected including, without limitation, risks regarding the COVID-19 pandemic, the availability and continuity of financing, the ability of the Company to adequately protect and enforce its intellectual property, the Company's ability to bring its products to commercial production, continued

growth of the global adaptive pathway medicine, natural health products and digital health industries, and the risks presented by the highly regulated and competitive market concerning the development, production, sale and use of the Company's products. Although the Company has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking information, there may be other factors that cause results not to be as anticipated, estimated or intended. There can be no assurance that such information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such information. These forward-looking statements are made as of the date hereof and the Company does not assume any obligation to update or revise them to reflect new events or circumstances save as required under applicable securities legislation.

Source: Mydecine Innovations Group Inc.