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# Mydecine Submits Pre-Investigational New Drug Briefing Package to the FDA for MYCO-001 Seamless Phase 2/3 Smoking Cessation Clinical Trial

DENVER, Feb. 01, 2022 (GLOBE NEWSWIRE) -- Mydecine Innovations Group (NEO: MYCO) (OTC: MYCOF) (FSE: 0NFA) ("Mydecine" or the "Company"), a biotechnology and digital technology company aiming to transform the treatment of mental health and addiction disorders, today announced in preparation for its FDA pre-Investigational New Drug (IND) meeting on February 28th, the company has submitted a pre-IND briefing package to the U.S. Food and Drug Administration (FDA) for a clinical study evaluating MYCO-001 in a structured smoking cessation treatment program.

The study will be led by Principal Investigator Dr. Matthew Johnson, Ph.D., Professor of Psychiatry and Behavioral Sciences at Johns Hopkins University. The university is the flagship site of the planned placebo-controlled study, which will assess the safety and efficacy of psilocybin-assisted psychotherapy utilizing MYCO-001 to treat tobacco addiction.

"We are excited to move forward on this important study, and our team has been working diligently to ensure that our pre-IND package is complete," said Mydecine CEO Josh Bartch. "Tobacco use is the greatest single, preventable cause of death in the world," he added, "yet there are few safe and effective treatments for nicotine addiction. As the only company currently investigating a psilocybin compound for smoking cessation, Mydecine is proud to be at the forefront of this research."

The planned study will build on previous smoking cessation studies conducted by Dr. Johnson and his team at Johns Hopkins University. In their ongoing trial, 59% of participants who received psychedelic-assisted therapy remained abstinent from smoking at 12 months, compared to only 28% of patients who received the transdermal nicotine patch.

Mydecine's Phase 2/3 study is projected to launch in Q2 2022 and will be looking at primary endpoints of three and six months. A combined-phase or operationally seamless clinical trial, such as this one, combines two or more phases into one study and uses results acquired throughout the trial to adjust the course of the study. This design can use resources more efficiently and often can be more informative than a traditional fixed study.

"Even with a wide variety of approved treatments on the market, tobacco addiction continues to remain largely untreated," added Mydecine CMO Dr. Rakesh Jetly. "With safety and efficacy concerns about current therapies, including the recall of the blockbuster treatment Chantix, there is a strong need for innovative and improved treatment options."

According to the Centers for Disease Control and Prevention (CDC), cigarette smoking is

responsible for one out of every five deaths in the United States, roughly 480,000 people every year. Approximately 34.1 million Americans currently smoke cigarettes. About 68% have stated they would like to quit smoking, and 55% have made an attempt to quit, yet only 7.5% are successful.

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**About Mydecine Innovations Group**
Mydecine Innovations Group™ (NEO:MYCO) (OTC:MYCOF) (FSE:0NFA) is a biotechnology and digital technology 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, 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.

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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.


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