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Mydecine Reports Positive Pre-IND Meeting With FDA For MYCO-001 Smoking Cessation Study

Company rapidly prepares to submit IND and Breakthrough Therapy Status Applications

DENVER, March 01, 2022 (GLOBE NEWSWIRE) -- Mydecine Innovations Group (NEO: MYCO) (OTC: MYCOF) (FSE: 0NFA) ("Mydecine" or the "Company"), a biotechnology company aiming to transform the treatment of mental health and addiction disorders, today announced a positive meeting with the Food and Drug Administration (FDA) regarding their Investigational New Drug (IND) and breakthrough therapy status applications.

The Company reported a meeting with the FDA on February 28th to review their IND application to administer MYCO-001, in combination with therapy, to humans as part of smoking cessation treatment. Leading drug and substance abuse researcher, Dr. Matthew Johnson of Johns Hopkins University, will serve as the lead investigator for this multi-site study.

"The data from John Hopkins University's ongoing studies assessing psychedelic-assisted therapy to treat nicotine addiction is showing efficacy rates 2-3 times higher than the current gold standard of treatment. Our team is eager to start collecting the data needed to bring an approved drug product to market that could potentially save millions of lives," said Mydecine Chief Medical Officer Dr. Rakesh Jetly.

"Mydecine plans to submit a request forBreakthrough Therapy designation with our IND submission. Psilocybin-assisted therapy has shown meaningful advantages over available medications for tobacco addiction including significant increases in safety and efficacy. We are looking forward to closely working with the FDA to bring safer and more effective therapy to the millions of people who are trying to quit smoking across the globe," said Mydecine's Senior Director of Clinical and Regulatory Affairs, Jessica Riggleman.

"We had an extremely positive meeting with the FDA in regards to our proposed smoking cessation study. The FDA provided helpful feedback on our study design that we will implement. We are now working rapidly in preparing our IND submission for the 2B portion of the study which we believe will be next month. Once cleared, we will move swiftly into patient recruitment. This is a study we have been diligently working on over the last two years and we're excited to continue moving it forward," said Mydecine CEO Josh Bartch.

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About Mydecine Innovations Group
Mydecine Innovations Group™ (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.

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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.