Mydecine Receives Conditional IRB Approval for Phase 2b Smoking Cessation Study

Clinical trial programs advance to further assess psychedelic-assisted psychotherapy utilizing lead drug candidate MYCO-001

DENVER, March 24, 2022 (GLOBE NEWSWIRE) -- **Mydecine Innovations Group Inc. (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 it has received conditional approval from the Institutional Review Board (IRB) for its multi-site Phase 2b smoking cessation trial. Johns Hopkins University will serve as the lead investigational site.

The Company reported the IRB has approved its Phase 2b smoking cessation study pending FDA approval of its Investigational New Drug (IND) application. Mydecine plans to submit the IND application in Q2 2022 and is hopeful it will go into effect 30 days after submission.

"We are beyond excited to share the news of our conditional IRB approval for our Phase 2b clinical trial. Upon the near-term clearance of our IND application, which is wholly owned by Mydecine, we will be the first commercial IND approved utilizing psilocybin for the indication of smoking cessation, and one of a small number of organizations with a commercial FDA IND approval, alongside COMPASS Pathways, MindMed, and Usona, for a Phase 2 or later stage study assessing a psychedelic compound for any indication. We have a strong patent and regulatory strategy to support this initiative as well as further subsequent approvals," said CEO Josh Bartch.

"This conditional approval marks a significant milestone not only for Mydecine but for people around the globe. The total economic cost of smoking has been estimated to be more than $300 billion per year in the United States alone. Our mission is to bring safer, more effective solutions to address nicotine dependence and other harmful addictions. This conditional approval brings us one step closer to potentially having a positive effect on millions of lives utilizing this innovative treatment program," said Mydecine's Chief Medical Officer Dr. Rakesh Jetly.

"Today's accomplishment speaks to the perseverance and dedication of our team as we continue to build on our clinical and commercial potential," added Mydecine's Senior Director of Clinical and Regulatory Affairs Jessica Riggleman. "Our success is built upon a strategic collaboration between our contract research organization, manufacturer, investigators, advisors

and regulatory consultants. We are diligently working together to submit our Investigational New Drug Application to the FDA for our multi-regional Phase 2b clinical trial."

The Company will move rapidly into the patient recruitment phase upon FDA clearance. Mydecine's Phase 2b study is investigating a primary endpoint of six months, indicating it could publish data as early as Q4 2023.

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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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