

MindMed Enrolls First Participant in a Study of its Session Monitoring System

NEW YORK, Jan. 18, 2022 /CNW/ -- Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (NEO: MMED), (DE: MMQ) (the "Company"), a clinical-stage biopharmaceutical company developing psychedelic-inspired therapies for the treatment of mental health and addiction, today announced that it has enrolled the first subjects into its Session Monitoring System (SMS-01) study evaluating the passive collection of sensory data during a consciousness-altering therapeutic session. SMS-01 utilizes MindMed's Session Monitoring System (MSMS), which it believes could have therapeutic applications in the treatment of psychiatric disorders.



MindMed recently consulted with the U.S. Food and Drug Administration's (FDA) Center for Devices, Radiological Health (CDRH) and Center for Drug Evaluation and Research (CDER) and received positive feedback supporting the planned development strategy. The objective of the meeting was to review the devices Indications for Use (IFU) statement, discuss the study design and facilitate early communication and guidance through the regulatory submission process.

"We have welcomed FDA input throughout the device development process, giving us a clear roadmap for the success and adoption of MSMS," said Daniel R Karlin, MD MA, Chief Medical Officer of MindMed. "The launch of this study is an important milestone for MindMed and for the future development of regulated devices and software-as-medical-devices (SaMD) products designed to support novel analyses of multimodal data in the delivery of psychiatric care. By refining the techniques used to capture, model and map these outputs, we aim to improve the experience of clinicians and outcomes for patients in the delivery of psychedelic and other perception-altering substances."

"Our team has worked incredibly hard to advance this product into the clinic and we remain dedicated to rolling out these novel approaches to improving mental health outcomes," said Todd M. Solomon, PhD, Head of Digital Psychiatry at MindMed. "We look forward to leveraging data from this study, and as we continue to advance our product development efforts, I would sincerely like to sincerely thank our team, study investigators, partners and most importantly the subjects who have agreed to participate in this study."

About MindMed Session Monitoring System (MSMS)

MindMed Session Monitoring System (MSMS) is a technological platform and product that provides the foundation for the development and implementation of a suite of regulated and unregulated products for use by clinicians and patients during treatment sessions that may also include the use of consciousness altering medications.

About MindMed

MindMed is a clinical-stage biopharmaceutical company developing the next generation of psychedelic-inspired therapies for the treatment of mental health and addiction. MindMed leverages rigorous drug development principles and advanced digital therapeutics to address these highly pressing, unmet patient needs. MindMed's differentiated pipeline features innovative treatments based on psychedelic substances including psilocybin, LSD, MDMA, DMT and an ibogaine derivative, 18-MC. Led by an executive team with extensive pharmaceutical industry experience, MindMed has forged strategic collaborations with leading research and academic institutions to accelerate new medicines to patients as quickly as possible. MindMed is headquartered in New York City. For more information, please visit https://mindmed.co/.

MindMed trades on the NASDAQ under the symbol MNMD and on the Canadian NEO Exchange under the symbol MMED. MindMed is also traded in Germany under the symbol MMQ.

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