December 9, 2021

MindMed Engages in Productive Pre-Submission Meeting with FDA for Development of the MindMed Session Monitoring System

NEW YORK, Dec. 9, 2021 /CNW/ -- Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (NEO: MMED), (DE: MMQ) (the "Company"), a leading biotech company developing psychedelic-inspired therapies recently met with the United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) with consultation from the Center for Drug Evaluation and Research (CDER) concerning several key points for ongoing development of the MindMed Session Monitoring System (MSMS) in a device pre-submission meeting that took place on October 25, 2021.

MindMed presented FDA with a working Indications for Use statement (IFU), and a development roadmap. These describe technology and infrastructure for the collection of precise, multimodal, multivalent data that can be processed via machine learning, artificial intelligence, signal processes, and other statistical methods to yield clinically meaningful output to satisfy the requirements of the IFU. FDA provided key feedback regarding the draft IFU and the research methods that will lay the foundation for regulatory submissions.

"We regard our regulators as key stakeholders throughout the device development process and seek meetings with FDA as early and often as feasible. These regulatory engagements provide the opportunity to thoroughly and continually discuss and assess alignment around the various considerations, which are essential to the success and adoption of MindMed's Session Monitoring System's regulated components" said Daniel R Karlin, MD MA, Chief Medical Officer of MindMed. "The FDA is supportive of our plans to develop regulated devices that would allow the use of novel analyses of multimodal data to capture, model, and map outputs that, if cleared, could be useful to clinicians and patients in the delivery of psychedelic and other perception-altering substances."

"We found the feedback from both CDRH and CDER to be invaluable as we look to bring our innovative products toward regulatory approval," said Todd M. Solomon, PhD, Head of Digital Psychiatry at MindMed. "We look forward to continued engagement across both

CDRH and CDER and believe this opportunity to collaborate across centers will benefit MindMed as we continue to refine our development plans."

About MindMed
MindMed is a clinical-stage psychedelic medicine biotech company that seeks to discover, develop and deploy psychedelic-inspired medicines and therapies to address addiction and mental illness. The Company is assembling a compelling drug development pipeline of innovative treatments based on psychedelic substances including psilocybin, LSD, MDMA, DMT and an Ibogaine derivative, 18-MC. The MindMed executive team brings extensive biopharmaceutical experience to MindMed's approach to developing the next generation of psychedelic-inspired medicines and therapies.

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.

Forward-Looking Statements
Certain statements in this news release related to the Company constitute "forward-looking information" within the meaning of applicable securities laws and are prospective in nature. Forward-looking information is not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as "will", "may", "should", "could", "intend", "estimate", "plan", "anticipate", "expect", "believe", "potential" or "continue", or the negative thereof or similar variations. Forward-looking information in this news release include, but are not limited to, statements regarding the development of the MindMed session monitoring system and bringing our innovative products toward regulatory approval. Although the Company believes that the expectations reflected in such forward-looking information are reasonable, such information involves risks and uncertainties, and undue reliance should not be placed on such information, as unknown or unpredictable factors could have material adverse effects on future results, performance or achievements of the Company. There are numerous risks and uncertainties that could cause actual results and the Company's plans and objectives to differ materially from those expressed in the forward-looking information, including history of negative cash flows; limited operating history; incurrence of future losses; availability of additional capital; lack of product revenue; compliance with laws and regulations; difficulty associated with research and development; risks associated with clinical trials or studies; heightened regulatory scrutiny; early stage product development; clinical trial risks; regulatory approval processes; novelty of the psychedelic inspired medicines industry; as well as those risk factors discussed or referred to herein and the risks described under the headings "Risk Factors" in the Company's filings with the securities regulatory authorities in all provinces and territories of Canada which are available under the Company's profile on SEDAR at www.sedar.com and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov. Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking information prove incorrect, actual results and future events could differ materially from those anticipated in such information. Although the Company has attempted to identify important risks, uncertainties and factors that could cause actual results to differ materially, there may be others that cause results not to be as anticipated, estimated or intended. These and all subsequent written and oral forward-looking information are based on estimates and opinions of management on the dates they are made and are expressly

qualified in their entirety by this notice. Except as required by law, the Company does not intend and does not assume any obligation to update this forward-looking information.

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