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MindMed Announces Initiation of Phase 1 Clinical Trial of Intravenous DMT

NEW YORK, July 28, 2021 /CNW/ -- MindMed (NASDAQ: MNMD) (NEO: MMED) (DE: MMQ), a leading biotech company developing psychedelic-inspired therapies, is pleased to announce the start of a Phase 1 clinical trial to assess the safety, pharmacokinetics and pharmacodynamics of DMT, a naturally occurring psychedelic substance and an active ingredient in ayahuasca. The outcome of this Phase 1 clinical trial is expected to facilitate potential future Phase 2 clinical trials of DMT in patients. The clinical trial is being conducted as an investigator-initiated study by Dr. Matthias Liechti as part of MindMed's ongoing collaboration with the UHB Liechti Lab. The Phase 1 clinical trial has received all necessary regulatory approvals in Switzerland and subject enrollment has been initiated.

MindMed is exploring DMT as a potential drug candidate given its potential advantages as a short-acting psychedelic. MindMed plans to study an intravenous administration method [during its Phase 1 clinical trial] that would induce a stable and prolonged DMT experience. The intravenous administration method may also allow greater control of the patient experience by enabling an acute termination of the psychoactive effects of DMT. DMT administration has a rapid onset and offset compared to the longer-acting psychedelic substances like psilocybin and LSD.

Dr. Miri Halperin Wernli, Executive President of MindMed, said, "We are very excited to start this study with Professor Matthias Liechti and University Hospital Basel. Currently no study has validly determined the elimination half-life of DMT or other pharmacokinetic parameters and our study will provide valuable information for future research on DMT as a tool to examine alterations of the mind. MindMed is exploring a number of psychedelic compounds as part of our mission to discover, develop and deploy psychedelic-inspired medicines and therapies to address mental illness and addiction. Our data driven approach drives our strategic choices for the development of both classical psychedelics and the very promising next generation novel chemical entities."

The goal of the clinical trial is to assess the safety, tolerability and dose-response of DMT, including an assessment of the difference between infusion conditions. The Phase 1 clinical trial will include 30 healthy subjects in a randomized 5-period crossover, double-blind, placebo-controlled design.

About MindMed

MindMed is a clinical-stage biotech company that discovers, develops and deploys 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. For more information: www.mindmed.co

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 start of MindMed's Phase 1 clinical trial of DMT, the successful outcome of the Phase 1 clinical trial, the ability to initiate a Phase 2 clinical trial of DMT, regulatory approvals, the effects of DMT, subject enrollment and the administration method of DMT. 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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