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MindMed Announces the Approval of Mescaline Study

BASEL, Switzerland, May 20, 2021 /CNW/ -- MindMed (Nasdaq: MNMD) (NEO: MMED) (DE: MMQ), a leading clinical stage psychedelic medicine company, announced today the approval by the local Swiss ethics committee of the first clinical trial evaluating the acute effects of different doses of mescaline and the role of the serotonin 5-HT_{2A} receptor in mescaline-induced altered states of consciousness (MDR-Study). The study will be conducted at the University Hospital Basel Liechti Lab, in Basel, Switzerland, and is planned to start this month.



Mescaline is a classic serotonergic hallucinogen, similar to LSD psilocybin, with a long, non-regulated history of spiritual use. However, modern regulated studies using validated psychometric tools and directly comparing different doses of mescaline including placebo are missing. We believe this phase 1 study will provide such data and an important basis for further research in the therapeutic potential of mescaline.

Dr. Matthias Liechti, PhD & M.D., professor for clinical pharmacology and internal medicine at the University of Basel stated, "Mescaline is an archetypical psychedelic with surprisingly little contemporary scientific information on its pharmacology and effects in humans. This study will, we believe, provide the first modern research data on mescaline regarding dosing and mechanism of action in humans."

The serotonin 2A (5-HT_{2A}) receptor is thought to primarily mediate acute alterations of consciousness induced by LSD and psilocybin. Mescaline also binds to the 5-HT_{2A} receptor with lower potency and higher activity compared to LSD. The present study will also explore the mechanism of action of mescaline in humans and specifically whether the acute psychoactive effects of mescaline in humans are mediated by 5-HT_{2A} receptors.

Compared with LSD and psilocybin, relatively high doses of 300-800 mg mescaline are needed to produce a prototypical hallucinogenic experience. Whether there are differences in the effects of mescaline compared with those of LSD or psilocybin will also be determined in additional studies.

The present study will primarily help to characterize the subjective effects of different doses of mescaline using modern psychometric outcome measures. It will also explore the role of the 5-HT2A receptor in mescaline-induced altered states of consciousness using the 5-HT2A receptor blocker ketanserin prior to the administration of a high dose of mescaline.

The study will use a double-blind, placebo-controlled, cross-over design with six different dosing conditions. The treatment order will be randomized and counter-balanced.

Dr. Miri Halperin Wernli, President of MindMed, added, "At present there are no modern studies that we are aware of using validated psychometric outcome measures that directly compare different doses of mescaline. With our rigorous clinical trial, we aim to characterize the subjective effects of different doses of mescaline and provide a description of the acute mescaline effects to help clarify the involvement of the 5-HT2A receptor in mescaline-induced altered states of consciousness in healthy people. We believe the drug will have a powerful effect on enhancing the communication between different parts of the brain in unique ways that are otherwise inaccessible to the conscious mind. As we move forward, further studies on patient populations will be targeted to help us distinguish the relationship between the drug-induced experience and its integration into the psychotherapeutic process. The hope is that this will then allow a better understanding of the behavioral changes and the unique effect of these powerful drugs on neuroplasticity."

About MindMed

MindMed is a clinical-stage psychedelic medicine 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, mescaline 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 includes statements regarding the timing of the start of the mescaline study; whether the study will provide the basis for further research in the therapeutic potential of mescaline, including whether that will include sufficient data on mescaline dosing and its mechanism of action in humans; the study's success in exploring the role of the 5-HT2A receptor in mescaline-induced altered states of consciousness; the study's ability to characterize the subjective effects of different doses of mescaline and provide a description of the acute

mescaline effects; the study's ability to help clarify the involvement of the 5-HT2A receptor in mescaline-induced altered states of consciousness in healthy people; the Company's belief that the drug will have an effect on enhancing the communication between different parts of the brain in unique ways that are otherwise inaccessible to the conscious mind; whether further studies on patient populations will occur; and whether the study will allow a better understanding of the behavioral changes and the unique effect of mescaline on neuroplasticity. 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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