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# MindMed Expands its Drug Development Pipeline with Launch of R(-)-MDMA Program

NEW YORK, Oct. 26, 2021 /CNW/ -- Mind Medicine (MindMed) Inc. (NASDAQ: MNMD) (NEO: MMED), (DE: MMQ); the "Company"), a leading biotech company developing psychedelic-inspired therapies, is pleased to announce an expansion of its pipeline with the launch of a program to develop R(-)-MDMA for the treatment of social anxiety and functioning in diagnoses that include Autism Spectrum Disorder (ASD). This program represents a significant expansion and diversification of MindMed's pipeline and furthers the Company's mission to bring innovative products to benefit patients and address unmet medical needs.



Social anxiety and impairments in social functioning are hallmarks of ASD, which occurs in approximately 2% of individuals in the US. At present, there are no approved therapies for the core symptoms of ASD and there remains a significant unmet need for novel therapies to support people with ASD. The economic cost of ASD in the US is predicted to reach \$461 billion by 2025, highlighting the need and opportunity for novel interventions. Beyond ASD, approximately 12% of the US general population experience Social Anxiety Disorder at some point in their lives, according to the National Institute of Mental Health.

MDMA, which is a racemic mixture of two structurally unique stereoisomers, R(-) and S(+), is currently in development for the treatment of Post-traumatic Stress Disorder (PTSD), and has demonstrated statistically significant positive results in a pivotal Phase 3 trial. Additionally, in a pilot clinical trial, participants with ASD showed strong and statistically significant improvements in social anxiety and functioning from short-term treatment with MDMA.

The two enantiomers of MDMA each have unique pharmacological activity and preclinical data suggests that the R(-) enantiomer maintains the acute pro-social and empathogenic benefits of racemic MDMA, while demonstrating fewer signs of stimulant activity, neurotoxicity, hyperthermia and abuse liability. This favorable profile suggests that R(-)-MDMA could have applications beyond those of racemic MDMA, including the potential for

novel more accessible delivery models and repeat dosing. From a safety perspective, the company has great confidence in the R(-) enantiomer based on its favorable preclinical pharmacology and the extent of prior human dosing of the racemic mixture, which provides valuable insight into the expected safety and tolerability of R(-)-MDMA.

MindMed plans to advance its R(-)-MDMA development program targeting US and EU registration and expects to initiate its first clinical trials in 2022. As a key initial study, MindMed and the Liechti Lab at University Hospital Basel (UHB) plan to initiate a comparative pharmacokinetics and pharmacodynamic clinical trial of R(-)-MDMA, S(+)-MDMA and R/S-MDMA in 2022. This double blind, placebo-controlled, crossover study will assess differences in acute and lasting effects between MDMA and its two enantiomers in healthy subjects and will provide important data on the optimal treatment model for R(-)-MDMA.

MindMed CEO Robert Barrow said, "The launch of our R(-)-MDMA program represents an important milestone in the continued progress of MindMed and builds on our commitment to developing psychedelics and psychedelic-inspired therapies to treat significant unmet medical needs. The compelling clinical efficacy of MDMA coupled with the unique pharmacological benefits of its R(-) enantiomer suggest that there is an enormous opportunity to bring this second generation psychedelic program to market with the potential for new clinical applications, novel treatment paradigms and enhanced accessibility."

MindMed Chief Medical Officer, Daniel R Karlin, MD, MA, said, "Our ability to enjoy life has a general dependency on feeling connected to other people, sharing experiences, and conveying shared emotions. There are a number of disorders and conditions, and even varieties of non-pathological states, in which individuals find it difficult to convey their own internal experience and emotions. They also may struggle to recognize the routine cues and signals that those around them use to convey emotions. These difficulties themselves can cause cycles of distressing anxiety, and in turn worsen both the sense, and the reality, of interpersonal disconnect. It is our intention with this new program to offer patients new hope for meaningful connection to the millions of people for whom social anxiety and functioning create day-to-day difficulties."

## **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 of 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 potential of R(-)-MDMA to treat social anxiety and functioning in diagnoses that include ASD and the benefits, safety, applications and plans for advancement and studies with respect to R(-)-MDMA . 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](http://www.sedar.com) and with the U.S. Securities and Exchange Commission on EDGAR at [www.sec.gov](http://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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