About Us

Investors

PRESS RELEASE

# MindMed Initiates Phase 2a LSD Trial for the Treatment of Adult ADHD

 Enrolling patients in proof-of-concept exploratory trial conducted in collaboration with the University Hospital Basel in Switzerland and Maastricht University in the Netherlands –

-Trial led by Dr. Matthias Liechti and Dr. Kim Kuypers, pioneers and leading global experts in the psychedelic landscape –

Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (NEO: MMED), (DE: MMQ) (the "Company"), a leading biotech company developing psychedelic-inspired therapies, today announced the initiation of Phase 2a proof-of-concept (POC) trial of lysergic acid diethylamide (LSD) in adult patients with attention deficit hyperactivity disorder (ADHD). The first site has been activated and patient enrollment is expected to start imminently. The POC trial will be conducted in collaboration with the University Hospital Basel in Switzerland and Maastricht University in the Netherlands and is designed to evaluate the therapeutic utility of repeated low doses of LSD.

"We are pleased to activate our first site and excited to initiate patient enrollment of our ADHD proof-of-concept trial," said Robert Barrow, Chief Executive Officer and Director of MindMed. "The study builds on the growing evidence demonstrating LSD has the potential to improve mood and selective cognitive processes. Further, low doses of LSD have been shown to be safe, well tolerated and have minimal effects on physiological parameters. In collaboration with our renowned clinical researchers and team of leading investigators, we look forward to driving this exploratory trial forward as part of our broader comprehensive LSD clinical development strategy."

Dr. Matthias Liechti, University Hospital Basel and co-primary investigator of the trial commented, "Psychedelics including LSD have shown beneficial and lasting effects on mood when given at single doses producing psychedelic effects. There is anecdotal evidence for possible benefits of low to very low doses of psychedelics given repeatedly. This is the first controlled study to validly evaluate therapeutic effects of very low doses of a psychedelic in patients." "We are very much looking forward to initiating our ADHD trial with repeated low doses of LSD, which will be conducted at two top European clinical therapeutic sites," said Dr. Miri Halperin Wernli, Executive President of MindMed. "We have designed a robust, randomized clinical trial to replicate and extend the promising findings of previously conducted smaller, open-label trials. This trial will evaluate our therapeutic regimen in a rigorously controlled setting and will help optimize the dosing schedule, compound selection and clinical management. Further, this trial will provide additional insight into the mechanisms by which psychedelics exert their therapeutic effects."

## Phase 2a Trial Design

This is a multicenter, randomized, double-blind, placebo-controlled Phase 2a trial evaluating the safety and efficacy of low-dose LSD as treatment for ADHD in adults. The trial plans to enroll a total of 52 patients that will receive 20µg of LSD every (dose schedule) or placebo for 6 weeks (twice a week on a 3/4-day schedule [± 1 day]). The primary endpoints are mean change from baseline in ADHD symptoms, as assessed by the AISRS after 6 weeks of treatment. The AISRS total score consists of 18 items from the original Attention- Deficit/Hyperactivity Disorder – Rating Scale (ADHD-RS), which were derived based on DSM-5 criteria for ADHD. The ADHD-RS includes 9 items that address symptoms of inattention, and 9 items that address symptoms of inattention, and 9 items that address symptoms to a worse severity of ADHD.

The trial will be led by Dr. Matthias Liechti, at University Hospital Basel, Switzerland and Dr. Kim Kuypers at Maastricht University, the Netherlands.

### About Adult ADHD

While ADHD is often associated with children and adolescents, adults living with the disease face numerous challenges from debilitating struggles with time management and impulsivity to mood swings and disorganization. Of the estimated 10 million American adults that have ADHD, it is projected that only 10.9% seek and receive treatment for their condition. Between 2007 and 2016 alone, the rate amongst adults increased by 123%. Adult ADHD comprises over 46.5% of the total ADHD medication market in the United States. The total U.S. market size for ADHD medications is currently valued at \$12.9 billion annually.

#### 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 forwardlooking 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 dimethyltryptamine (DMT), the business and the therapeutic potential of MindMed's product candidates, the ability to successfully execute and delivery on the R(-)-MDMA Program, the ability to achieve success with our collaborations with Sphere Health and Forian, the successful outcome of the Phase 1 clinical trial of DMT, 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 forwardlooking 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.

For Media: media@mindmed.co

For Investors: ir@mindmed.co

• т





PRESS RELEASE MindMed Appoints Robert Barrow as Chief Executive Officer and Director

#### **Browse more articles**



PRESS RELEASE

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

BACK TO ALL NEWS



PRESS RELEASE

MindMed to Participate at the Benzinga Global Small Cap Conference

# MindMed

MindMed US Headquarters One World Trade Center Suite 8500 New York, NY 10007, USA

f 🖸 🎔 🗖 in

NEO: MMED NASDAQ: MNMD

#### **Our Medicines**

Experiential Therapies Psychedelic Inspired Next-Gen R&D

Anxiety Addiction Adult ADHD

Our Focus

Press Releases Downloads Corp. Governance Financials

Investors

About Us

News / Blog Our Team Partnerships Contact Us

© 2021 Mind Medicine Inc. All rights reserved. Legal Disclaimers د الله المحدقة Accessibility Information



Get MindMed Updates: ( you@yours.com

 $\square$