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MindMed Announces First Patient Dosed in Phase 3 Emerge Study of MM120 in Major Depressive Disorder (MDD)

- Emerge is the first Phase 3 study of lysergide D-tartrate (LSD) in MDD; primary endpoint will measure change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) score at Week 6 between MM120 Orally Disintegrating Tablet (ODT) 100 µg and placebo -

- Emerge builds on positive Phase 2b study results in generalized anxiety disorder (GAD), which showed MM120's potential antidepressant effects -

- Topline data from the 12-week double-blind period anticipated in the second half of 2026 -

NEW YORK--(BUSINESS WIRE)-- Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (the "Company" or "MindMed"), a late-stage clinical biopharmaceutical company developing novel product candidates to treat brain health disorders, today announced that the first patient has been dosed in its Phase 3 Emerge study evaluating MM120 ODT, a proprietary, pharmaceutically optimized form of LSD for the treatment of MDD. Emerge will evaluate the efficacy and safety of MM120 ODT 100 µg versus placebo and is expected to enroll approximately 140 participants in the United States. Emerge is the third Phase 3 study of MM120 ODT, with the Voyage and Panorama studies in GAD already underway.

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Image of MM120 Orally Disintegrating Tablets

"In our Phase 2b study, MADRS score improvements after a single MM120 100 µg dose were clinically and statistically significant compared to placebo, providing meaningful benefits to participants. Having dosed the first participant in the Phase 3 Emerge study, we are excited for the therapeutic potential that MM120 ODT shows for the 21 million people in the U.S. affected by MDD," said Daniel R. Karlin, M.D., M.A., Chief Medical Officer of MindMed. "By running our MDD and GAD Phase 3 studies concurrently, we can leverage the shared symptomatology between these conditions to more effectively match participants to the appropriate study based on their clinical presentation."

The Phase 3 development program for MM120 ODT in MDD is anticipated to include two pivotal clinical trials. The first, the 52-week Emerge study, will be conducted in two parts: Part A, a 12-week, randomized, double-blind, placebo-controlled, parallel-group study assessing the efficacy and safety of a single dose of MM120 ODT versus placebo; and Part B, a 40-week extension period during which participants will be eligible for open-label treatment with MM120 ODT based on symptom severity. In Part A, participants will be randomized 1:1 to receive MM120 ODT 100 µg or placebo. The primary endpoint of Emerge is the change from baseline in MADRS score at week 6 between MM120 ODT 100 µg and

placebo. The design and timing of a second MDD trial will be informed by the progress from Emerge and additional regulatory discussions.

"The initiation of Emerge will allow the assessment of the potential of MM120 ODT in the treatment of MDD, a disorder associated with significant increased and premature morbidity and mortality, and reduced quality of life. Many patients with MDD are not fully helped by current therapies, making this study an important step in the search for more effective treatments," said Paul Summergrad, M.D., Professor of Psychiatry and Medicine at Tufts University School of Medicine and Chairman Emeritus of the department of psychiatry at Tufts Medical Center and a member of the MindMed Scientific Advisory Board.

About Major Depressive Disorder (MDD)

Major Depressive Disorder (MDD) is the second-most common mental health disorder in the U.S., with over 21 million adults experiencing a major depressive episode (MDE) each year.[1,2] This disorder, a leading cause of disability worldwide,[3] brings persistent feelings of worthlessness, fatigue, and recurrent thoughts of death[4] while increasing long-term mortality risk by 40%.[5] MDD also carries a $326 billion annual economic burden in the U.S., driven by healthcare costs and lost productivity.[6] Yet, fewer than half of those affected receive adequate pharmacotherapy, and only about one-third achieve remission with first-line treatments.[7,8]

About MM120 Orally Disintegrating Tablet (ODT)

MM120 ODT (lysergide D-tartrate or LSD) is a synthetic ergotamine belonging to the group of classic, or serotonergic, psychedelics, which acts as a partial agonist at human serotonin-2A (5-HT2A) receptors. MM120 ODT is MindMed's proprietary and pharmaceutically optimized form of LSD. MM120 ODT is an advanced formulation incorporating Catalent's Zydis® ODT fast-dissolve technology which has a unique clinical profile with more rapid absorption, improved bioavailability and reduced gastrointestinal side effects.

The MM120 ODT Phase 3 clinical development program includes the Voyage and Panaroma studies in generalized anxiety disorder (GAD) and the Emerge study in major depressive disorder (MDD). Additional clinical indications are under consideration. MindMed's Phase 2b study of MM120 for GAD, MMED008, met its primary and key secondary endpoints and demonstrated rapid, clinically meaningful, and statistically significant improvements on the Hamilton Anxiety Rating Scale (HAM-A) at Week 4 and Week 12, with a 65% clinical response rate and 48% clinical remission rate sustained to Week 12 in the MM120 100 µg cohort. Results from the assessment of several additional secondary endpoints were pre-specified, including the change from baseline compared to placebo in Montgomery-Åsberg Depression Rating Scale (MADRS) scores, which measure the severity of depression symptoms. MDD and depressive symptoms are common co-morbidities in people with GAD. MADRS score improvements in the 100 µg arm of the study were clinically and statistically significant compared to the placebo group, with a difference of 5.7 points ($p \leq 0.05$) at week 4 and a difference of 6.4 points ($p \leq 0.05$) at week 12. MM120 was generally well-tolerated in this study, with most adverse events rated as mild to moderate, transient, and occurring on the dosing day and being consistent with the expected acute effects of the trial drug.

Based on the significant unmet medical need in the treatment of GAD along with the initial clinical data from the Phase 2b study and other research conducted by MindMed, the U.S.

Food and Drug Administration has granted Breakthrough Therapy Designation for the MM120 program in GAD. MindMed has also been granted an Innovation Passport for the potential treatment of GAD under the United Kingdom Innovative Licensing and Access Pathway (ILAP) by the U.K. Medicines and Healthcare products Regulatory Agency. The Innovation Passport is the entry point to the ILAP, which aims to accelerate time to market and facilitate patient access to medicines in the U.K.

About MindMed

MindMed is a late-stage clinical biopharmaceutical company developing novel product candidates to treat brain health disorders. Our mission is to be the global leader in the development and delivery of treatments that unlock new opportunities to improve patient outcomes. We are developing a pipeline of innovative product candidates, with and without acute perceptual effects, targeting neurotransmitter pathways that play key roles in brain health. MindMed trades on NASDAQ under the symbol MNMD.

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, but is not limited to, statements regarding the Company's anticipated topline readout (Part A results) for the Phase 3 Emerge study of MM120 ODT in MDD in the second half of 2026; the Company's plans to conduct a second Phase 3 study in MDD; the Company's expectations to enroll approximately 140 participants in the Emerge study; the Company's beliefs regarding potential benefits of its product candidates; the Company's expectations regarding potential additional indications for MM120. 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; compliance with laws and regulations; legislative and regulatory developments, including decisions by the Drug Enforcement Administration and states to reschedule any of our product candidates, if approved, containing Schedule I controlled substances, before they may be legally marketed in the U.S.; the impact of potential tariffs on pharmaceutical products; difficulty associated with research and development; risks associated with clinical studies or studies; heightened regulatory scrutiny; early stage product development; clinical study risks; regulatory approval processes; novelty of the psychedelic inspired medicines industry; ability to maintain effective patent rights and other intellectual property protection; as well as those risk factors discussed or referred to herein and the risks described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 under headings such as "Special Note Regarding Forward-Looking Statements," and "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other filings and furnishings made by the Company with the securities regulatory authorities in all provinces and territories of Canada which are available under the Company's profile on SEDAR+ at www.sedarplus.ca and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov. Except as

required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events, changes in expectations or otherwise.

References:

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