December 16, 2024

MindMed Announces First Patient Dosed in Phase 3 Voyage Study of MM120 in Generalized Anxiety Disorder (GAD)

- Voyage is the first-ever Phase 3 study of lysergide D-tartrate (LSD) with the primary endpoint measuring the change from baseline in the Hamilton Anxiety Rating Scale (HAM-A) score at week 12 for MM120 Orally Disintegrating Tablet (ODT) 100 µg vs placebo -

- Study builds on positive Phase 2b study results presented at the American Psychiatric Association's Annual Meeting in May 2024 -

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

NEW YORK--(BUSINESS WIRE)-- Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (the "Company" or "MindMed"), a clinical-stage biopharmaceutical company developing novel product candidates to treat brain health disorders, today announced that the first patient has been dosed in its Phase 3 Voyage study of MM120 ODT, a pharmaceutically optimized form of lysergide D-tartrate (LSD) for the treatment of GAD. Voyage is the first of two Phase 3 studies in GAD evaluating the efficacy and safety of MM120 ODT versus placebo and is expected to enroll approximately 200 participants in the United States. The Panorama study, the second Phase 3 trial, will be conducted in the U.S. and Europe and is on track to initiate in the first half of 2025.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20241216046321/en/



"Today marks a pivotal moment in our journey towards advancing a novel treatment option for the 20 million people[1] in the U.S. living with GAD. Building on our scientifically rigorous Phase 2b study, which demonstrated efficacy that far exceeds today's standard of care and a favorable tolerability profile, our Phase 3 studies are designed to adhere to the

Representative Image of MM120 ODT/Courtesy of Catalent

highest clinical and ethical standards and are in alignment with guidance from the U.S. Food and Drug Administration," said Daniel R. Karlin, M.D., M.A., Chief Medical Officer of MindMed.

The 52-week Voyage study will be conducted in two parts: Part A, a 12-week, randomized, double-blind, placebo-controlled, parallel group period; 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. The primary endpoint of Voyage will measure the change from baseline in HAM-A at Week 12, which is consistent with the durable clinical effect observed in the Phase 2b study.

"It is critical to continue to develop new and effective treatment options for patients with GAD, a debilitating condition where there is an urgent need for transformational innovation," said David Feifel, M.D., Ph.D., Professor Emeritus of Psychiatry at the University of California, San Diego and Director of the Kadima Neuropsychiatry Institute in La Jolla, California and an investigator in the Voyage study. "The design of the MM120 ODT Phase 3 clinical program directly builds on the robust Phase 2b study results and incorporates best-in-class methodologies to mitigate the impact of functional unblinding, including the use of independent central raters blinded to both treatment assignment and visit number. The studies have also been designed to isolate the standalone drug effect of MM120 ODT from other psychotherapeutic intervention and follow industry best practices for safety monitoring."

About Generalized Anxiety Disorder (GAD)

GAD is a common condition associated with significant impairment that adversely affects millions of people. GAD results in fear, continuing anxiety, and a constant feeling of being overwhelmed. It is characterized by excessive, persistent, and unrealistic worry about everyday things. Approximately 10% of U.S. adults, representing around 20 million people[1], currently suffer from GAD. This underdiagnosed and underserved mental health disorder is associated with less accomplishment at work and reduced labor force participation. Despite the significant personal and societal burden of GAD, there has been little innovation in the treatment of GAD in the past several decades, with the last new drug approval occurring in 2007.

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, 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. 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 & Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for the MM120 program in GAD.

About MindMed

MindMed is a clinical-stage 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 for the Voyage study (Part A results) in the first half of 2026; the Company's expectation to enroll approximately 200 participants in the Voyage study; the Company's expectation to initiate the Panorama Study in the first half of 2025; the Company's beliefs regarding potential benefits of its product candidates; anticipated upcoming milestones, trials and studies; and potential additional indications for MM120 ODT. 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; 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 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 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:

1. Ringeisen, H., Edlund, M. J., Guyer, H., Geiger, P., Stambaugh, L. F., Dever, J. A., Liao, D., Carr, C. M., Peytchev, A., Reed, W., McDaniel, K., & Smith, T. K. (2023). *Mental and Substance Use Disorders Prevalence Study: Findings report*. RTI International.

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