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MindMed Announces First Patient Dosed in Panorama, the Second Pivotal Phase 3 Study of MM120 in Generalized Anxiety Disorder

- *Panorama is the second Phase 3 trial 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 -*
- *Panorama builds on positive Phase 2b study results presented at the American Psychiatric Association's Annual Meeting in May 2024 and will be conducted at sites in the US and Europe -*
- *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 Panorama, its second Phase 3 study evaluating MM120 ODT, a proprietary, pharmaceutically optimized form of LSD for the treatment generalized anxiety disorder (GAD). The Panorama study will evaluate the efficacy and safety of MM120 ODT versus placebo, will be conducted in the United States and Europe, and is expected to enroll approximately 250 participants.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20250127889062/en/>

“This is an incredible time for MindMed, and we are optimistic about what lies ahead as we embark on our second Phase 3 study for MM120 ODT in GAD only weeks after the successful launch of our first Phase 3 study, Voyage,” said Dan Karlin, M.D., M.A., Chief Medical Officer of MindMed. “MM120 ODT represents a potentially life-changing treatment for people living with GAD, and if our Phase 3 development program is successful, it could offer a differentiated and compelling option for one of the most significant unmet needs in psychiatry. We aspire to deliver a truly transformational treatment that we believe has the potential to change the trajectory of the ongoing brain health epidemic.”

The clinical trial design of the 52-week Panorama study is aligned to Voyage and 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. Participants will be randomized 2:1:2 to receive MM120 ODT 100 µg, MM120 ODT 50 µg, or placebo. The 50 µg arm serves to confound participants' ability to accurately assess the dose condition to which they have been randomized. This approach builds on the MM120 Phase 2b study, which the Company believes demonstrated that the clinical activity of



Image of MM120 Orally Disintegrating Tablets (Photo: Business Wire)

MM120 was not attributable to functional unblinding and aligns with FDA guidance regarding the use of complementary designs across our Phase 2 and 3 studies. The primary endpoint of Panorama will measure the change from baseline in HAM-A at Week 12 between MM120 ODT 100 µg and placebo, which is consistent with the durable clinical effect observed in the MM120 Phase 2b study.

“GAD is a common and debilitating disorder, as we have shown that it impairs various cognitive abilities, and many patients are not sufficiently helped by currently available treatments.¹ There is an urgent need for different approaches. The Panorama study builds on the results of MindMed’s Phase 2b study, which showed a rapid and sustained response to a single dose of MM120, demonstrating its potential as a promising treatment for GAD,” said Philip Gorwood, M.D., Ph.D., Professor of Psychiatry at Sainte-Anne Hospital and Paris Cité University, France. “Panorama, which is consistent with the design of the Phase 2b study, has the potential to be a transformative change in the way we understand and treat brain health disorders, offering acute but also lasting benefits to patients who have long been frustrated with current standards of care.”

About Generalized Anxiety Disorder (GAD)

GAD is a common disorder 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 people², currently suffer from GAD. This underdiagnosed and underserved mental health disorder is associated with significant impairment, 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-HT_{2A}) 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 Panorama 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 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 for the Panorama study (Part A results) in the second half of 2026; the Company's expectation to enroll approximately 250 participants in the Panorama study; 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. Baussay A, Di Lodovico, Poupon D, Doublet M, Ramoz N, Duriez P, Gorwood P (2024) The capacity of cognitive tests to detect generalized anxiety disorder (GAD), a pilot study. *J Psychiatr Res*, Jun; 174: 94-100.
2. 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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