June 20, 2024

MindMed Announces Constructive End-of-Phase 2 Meeting with U.S. FDA for MM120 in Generalized Anxiety Disorder (GAD)

-Aligned on requirements for Phase 3 clinical development of MM120 for the treatment of GAD-

-Initiation of Phase 3 program remains on schedule to begin in second half of 2024-

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 the completion of the End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA), supporting the advancement of MM120 (lysergic acid diethylamide [LSD] D-tartrate) into pivotal trials for the treatment of adults with GAD.

"Following a constructive End-of-Phase 2 meeting with the FDA, we are pleased to have reached alignment on our Phase 3 development strategy for MM120 in GAD," said Rob Barrow, Chief Executive Officer of MindMed. "This marks a significant milestone for MindMed and for the millions of individuals affected by GAD. We are on schedule to initiate our Phase 3 clinical program for MM120 oral dissolving tablet (ODT) in GAD in the second half of this year and look forward to sharing additional details on the design of our pivotal program in the coming months."

The EOP2 meeting was supported by results from MindMed's completed Phase 2b clinical trial, MMED008. The multi-center, randomized, double-blind, parallel-group, dose-finding study was designed to assess the effect of four doses of MM120 for the treatment of anxiety symptoms in participants diagnosed with GAD. In the trial, MM120 met its primary and key secondary endpoints and demonstrated a 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 trial, 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.

"On behalf of the 20 million people in the U.S. – and millions more worldwide – who are living with GAD, we are incredibly excited for the therapeutic potential that MM120 shows based on the data from the previously completed Phase 2b MMED008 trial," said Daniel R. Karlin, MD, MA, Chief Medical Officer of MindMed. "Few treatment options have shown robust activity in GAD, with the last new FDA approval occurring in 2007. We are committed to bringing MM120 to people living with GAD and are excited to move into the next phase of our development program."

About MM120

LSD (lysergide) is a synthetic ergotamine belonging to the group of classic, or serotonergic, psychedelics, which acts as a partial agonist at human serotonin-2A (5-hydroxytryptamine-2A [5-HT2A]) receptors. MindMed is developing MM120, the tartrate salt form of lysergide, for GAD and is exploring its potential applications in other serious brain health disorders.

About Generalized Anxiety Disorder (GAD)

GAD is a common condition associated with significant impairment that adversely affects millions of people. GAD results in fear, persistent 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, currently suffer from GAD. This underdiagnosed and underserved indication 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 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 disorders. 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 timing of the initiation of a potential Phase 3 clinical trial of MM120 and the potential benefits of the Company’s product candidates. There can be no guarantees regarding the timing or results of the potential Phase 3 clinical trials for MM120 for the treatment of GAD or that, following any such trials, MM120 will receive the necessary regulatory approvals. 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 its 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 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,” “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.

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