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MindMed Receives FDA Breakthrough Therapy Designation and Announces Positive 12-Week Durability Data From Phase 2B Study of MM120 for Generalized Anxiety Disorder

-A single oral administration of MM120 100 µg met its key secondary endpoint and maintained a clinically and statistically significant HAM-A reductions compared to placebo at 12 weeks with a 65% clinical response rate and 48% clinical remission rate-

-MindMed plans to hold an End-of-Phase 2 meeting with the U.S. Food & Drug Administration (FDA) in the first half of 2024 and initiate its Phase 3 clinical program in the second half of 2024-

-MindMed will host a webcast to discuss data from its Phase 2b study at 8:00 am ET-

NEW YORK--(BUSINESS WIRE)-- **Mind Medicine (MindMed) Inc.** (NASDAQ: MNMD), (Cboe Canada MMED), (the “Company” or “MindMed”), a clinical stage biopharmaceutical company developing novel product candidates to treat brain health disorders, today announced that FDA has granted breakthrough designation to its MM120 (lysergide d-tartrate) program for the treatment of generalized anxiety disorder (GAD). The Company also announced that its Phase 2b study of MM120 in GAD met its key secondary endpoint, and 12-week topline data demonstrated clinically and statistically significant durability of activity observed through Week 12.

MindMed previously announced rapid, clinically meaningful, and statistically significant improvements on the Hamilton Anxiety rating scale (HAM-A) compared to placebo at Week 4, which was the trial’s primary endpoint. MM120 was administered as a single dose in a monitored clinical setting with no additional therapeutic intervention.

“I’ve conducted clinical research studies in psychiatry for over two decades and have seen studies of many drugs under development for the treatment of anxiety. That MM120 exhibited rapid and robust efficacy, solidly sustained for 12 weeks after a single dose, is truly remarkable,” stated David Feifel, MD, PhD, 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 MM120 study. “These results suggest the potential MM120 has in the treatment of anxiety, and those of us who struggle every day to alleviate anxiety in our patients look forward to seeing results from future Phase 3 trials.”

MM120 100 µg – the dose with optimal clinical activity observed in the trial – demonstrated a 7.7-point improvement over placebo at Week 12 (-21.9 MM120 vs. -14.2 placebo; $p < 0.003$)

Cohen's $d=0.81$), with a 65% clinical response rate and a 48% clinical remission rate sustained to Week 12. Clinical Global Impressions - Severity (CGI-S) scores on average improved from 4.8 to 2.2 in the 100- μg dose group, representing a two-category shift from 'markedly ill' to 'borderline ill' at Week 12 ($p<0.004$). This clinical activity was rapid, observed as early as study day 2, and durable with further improvements observed in mean HAM-A or CGI-S scores between Weeks 4 and 12.

Based on the significant unmet medical need in the treatment of GAD – especially in patients who do not respond to or tolerate currently available medications – along with the initial clinical data from Phase 2b and other research conducted by MindMed, the U.S. Food & Drug Administration (FDA) has designated MM120 for GAD as a breakthrough therapy. The Company plans to hold an End-of-Phase 2 meeting with the FDA in the first half of 2024 and initiate a Phase 3 clinical program in the second half of 2024.

“The FDA’s decision to designate MM120 as a breakthrough therapy for GAD and the durability data from our Phase 2b study provide further validation of the important potential role this treatment can play in addressing the huge unmet need among individuals living with GAD,” said Robert Barrow, Chief Executive Officer and Director of MindMed. “We are committed to bringing MM120 to people living with GAD and delivering on the potential of our pipeline to treat serious brain health disorders.”

In the Phase 2b study, known as MMED008, MM120 was generally well-tolerated with most adverse events rated as mild to moderate, transient and occurring on dosing day, and being consistent with expected acute effects of the study drug. The most common adverse events (at least 10% incidence in the high dose groups) on dosing day included illusion, hallucinations, euphoric mood, anxiety, abnormal thinking, headache, paresthesia, dizziness, tremor, nausea, vomiting, feeling abnormal, mydriasis and hyperhidrosis.

Prior to treatment with MM120, study participants were clinically tapered and then washed out from any anxiolytic or antidepressant treatments and did not receive any form of study-related psychotherapy for the duration of their participation in the study.

“As a clinician and clinical researcher, I applaud the way this study was designed by MindMed to isolate the effect of MM120 by removing confounding variables like additional medications and psychotherapy,” said Reid Robison, MD, Psychiatrist and Chief Clinical Officer at Numinus (TSX:NUMI) who has served as adjunct faculty at the University of Utah for the last 12 years and was an investigator in the MM120 study. “It gives me confidence in the data and the positive results give me hope that this may translate into meaningful benefits for my patients.”

The primary data analyses from MMED008 have been accepted for presentation at the American Psychiatric Association’s annual meeting, which will be held in New York on May 4-8, 2024. The study is also being submitted for publication in a leading medical journal.

Conference Call and Webcast

MindMed management will host a webcast at 8:00 am ET today to discuss the Phase 2b results of MM120 in GAD. The webcast and slides will be accessible live under “News & Events” on the Investors page of the Company’s website at <https://ir.mindmed.co/> or by clicking [here](#). A replay of the event will be available on MindMed’s website. The webcast will

be archived on the Company's website for at least 30 days after the conference call.

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, an underdiagnosed and underserved indication that 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 2004.

About MMED008

MMED008 was a multi-center, parallel, randomized, double-blind, placebo-controlled, dose-optimization study. The trial enrolled 198 participants who were randomized to receive a single administration of MM120 at a dose of 25, 50, 100 or 200 µg or placebo. The full analysis set (FAS) for the trial included 194 subjects, those that had at least one valid post-baseline Hamilton Anxiety rating scale (HAM-A) score. Subjects enrolled in the trial presented with severe GAD symptoms (average baseline HAM-A scores of approximately 30). The study's main objective was to determine the dose-response relationship of four doses of MM120 versus placebo as measured by the change in HAM-A from Baseline to Week 4. The key secondary objective of the study was to determine the dose-response relationship of four doses of MM120 versus placebo as measured by the change in HAM-A from Baseline to Week 8. Secondary objectives, measured up to 12 weeks after the single administration, include assessments of anxiety symptoms, safety and tolerability, and other measures of efficacy and quality of life. More information about the trial is available on the MindMed website (mindmed.co) or on clinicaltrials.gov (NCT05407064).

About MM120

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-HT_{2A}]) receptors. MindMed is developing MM120 (lysergide D-tartrate), the tartrate salt form of lysergide, for GAD and is exploring its potential applications in other serious brain health disorders.

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 and on the Cboe Canada (formerly known as the NEO Exchange, Inc.) under the symbol MMED.

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 anticipated upcoming milestones, and progress of trials and studies; results and timing of and reporting of full data from the Company’s Phase 2b clinical trial of MM120; timing of a potential End-of-Phase-2 meeting with the FDA; 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 results of the potential Phase 3 clinical trial or that, following any such trial, 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 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.sedar.com 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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