

MindMed Announces Positive Topline Results from Phase 2b Trial of MM-120 in Generalized Anxiety Disorder

- Trial met its primary endpoint with MM-120 demonstrating a statistically significant dose-dependent improvement in HAM-A scores four weeks after a single-dose –
- MM-120 100 µg demonstrated a clinically and statistically significant HAM-A reduction of 21.3 points, representing a 7.6-point improvement over placebo at Week 4 ($p=0.0004$, Cohen's d effect size = 0.88) –
- Clinical response rate of 78% in 100 µg and 200 µg dose groups and 50% clinical remission rate in the 100 µg dose group at Week 4 –
- MM-120 was generally well-tolerated with mostly mild-to-moderate adverse events that occurred on dosing day –
- Company 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 a Phase 3 clinical program in the second half of 2024 –
- Conference call and webcast to take place today at 8:30 am EST –

NEW YORK--(BUSINESS WIRE)-- **Mind Medicine (MindMed) Inc.** (NASDAQ: MNMD), (NEO: MMED), (the "Company" or "MindMed"), a clinical stage biopharmaceutical company developing novel product candidates to treat brain health disorders, today announced positive topline results from its Phase 2b clinical trial of MM-120 (lysergide d-tartrate) in generalized anxiety disorder (GAD). The trial met its primary endpoint, with MM-120 demonstrating statistically significant and clinically meaningful dose-dependent improvements on the Hamilton Anxiety rating scale (HAM-A) compared to placebo at Week 4. MM-120 was administered as a single-dose in a monitored clinical setting with no additional therapeutic intervention.

MM-120 100 µg – the dose achieving the highest level of clinical activity – demonstrated a 7.6-point reduction compared to placebo at Week 4 (-21.3 MM-120 vs. -13.7 placebo; $p<0.0004$; Cohen's $d=0.88$). Clinical Global Impressions - Severity (CGI-S) scores on average improved from 4.8 to 2.4 in the 100 µg dose group, representing a two-category shift from 'markedly ill' to 'borderline ill' at Week 4 ($p<0.001$). This clinical activity was observed to be rapid and durable beginning on Day 2 and continuing through Week 4 with no loss of activity observed on either HAM-A or CGI-S.

"We are excited by the strong positive results for MM-120 in GAD, particularly given that this is the first study to assess the standalone drug effects of MM-120 in the absence of any psychotherapeutic intervention. These promising findings represent a major step forward in

our goal to bring a paradigm-shifting treatment to the millions of patients who are profoundly impacted by GAD,” said Robert Barrow, Chief Executive Officer and Director of MindMed. “We look forward to sharing additional study results in the coming months – including topline 12-week results in the first quarter of 2024 – and working closely with FDA as we finalize the Phase 3 development program for MM-120 in GAD. I would like to thank all of the participants in the study as well as the study investigators and our clinical development team, whose dedication made this important milestone possible.”

Daniel Karlin, MD, MA, Chief Medical Officer of MindMed said, “Generalized anxiety disorder is a common condition associated with significant impairment that adversely affects millions of people and there remains a serious unmet need for this patient population. The pharmaceutical industry has largely ignored GAD over recent decades as it has proved extremely difficult to target. Few new treatment options have shown robust activity in GAD since the last new drug approval in 2004, making the strong, rapid, and durable clinical activity of a single dose of MM-120 observed in the trial particularly notable. We believe this study is the first to rigorously assess the efficacy of a drug candidate in this class in the absence of a concurrent therapeutic intervention, which brings hope to the millions of people suffering from GAD and provides additional evidence that MM-120 may play an important role in revolutionizing the treatment of brain health disorders.”

Additional secondary and exploratory endpoints included in the primary topline results included HAM-A response and remission rates and Clinical Global Impressions - Severity (CGI-S) scores. Clinical response (50% or greater improvement in HAM-A) at Week 4 was achieved in 78% of participants treated with MM-120 (100 µg or 200 µg) compared to 31% for placebo. Clinical remission (HAM-A ≤ 7) at Week 4 was achieved in 50% of participants treated with MM-120 100 µg. CGI-S scores demonstrated a statistically significant and clinically meaningful improvement compared to placebo in the 100 µg ($p \leq 0.001$) and 200 µg ($p \leq 0.01$) dose groups. On average, participants receiving MM-120 (100 µg or 200 µg) experienced a 2-unit improvement in the CGI-S score at Week 4, with statistically significant improvements observed as early as one day after treatment and continuing at all evaluated timepoints through Week 4.

MM-120 was generally observed to be well tolerated, with mostly transient mild-to-moderate adverse events (AEs) that appear consistent with the pharmacodynamic effects of MM-120. The overall four-week completion rate in the trial was approximately 90% and was 97.5% in the high dose groups, and no participants in the high dose groups discontinued due to an adverse event through Week 4. The most common adverse events (at least 10% incidence in the high dose groups) occurred on dosing day and included illusion, hallucinations, euphoric mood, anxiety, thinking abnormal, headache, paraesthesia, dizziness, tremor, nausea, vomiting, feeling abnormal, mydriasis and hyperhidrosis.

The Company expects that results of this study will support the advancement of MM-120 into Phase 3 clinical development for GAD. The Company plans to hold an End-of-Phase 2 meeting with the FDA in the first half of 2024 and expects to initiate Phase 3 clinical trials in the second half of 2024. The Company expects to present additional topline 12-week data from the study in the first quarter of 2024 and to present full results at a scientific meeting in 2024.

Conference Call and Webcast

MindMed management will host a conference call at 8:30 AM EST today to discuss the results of MM-120 in GAD. Individuals may participate in the live call via telephone by dialing (877) 407-3982 (domestic) or (201) 493-6780 (international). The webcast can be accessed live [here](#) on the News & Events page in the Investors section of the MindMed website, <https://mindmed.co/>. The webcast will be archived on the Company's website for at least 30 days after the conference call.

About Study MMED008

Study MMED008 is 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 MM-120 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 primary objective of the study was to determine the dose-response relationship of four doses of MM-120 versus placebo as measured by the change in HAM-A from Baseline to Week 4. Secondary objectives, measured up to 12 weeks after the single administration, include assessments of anxiety symptoms, safety and tolerability, as well as 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 (identifier NCT05407064).

About MM-120

Lysergide is a synthetic tryptamine 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 MM-120 (lysergide D-tartrate), the tartrate salt form of lysergide, for GAD and ADHD.

About Generalized Anxiety Disorder

GAD is a brain health disorder that 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 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 MM-120; timing of a potential End-of-Phase-2 meeting with the FDA; timing of the initiation of a potential Phase 3 clinical trial of MM-120; and the potential benefits of the Company’s product candidates. 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, 2022, the Company’s Quarterly Reports on Form 10-Q for the periods ended March 31, 2023, June 30, 2023 and September 30, 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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20231214537387/en/>

For Media & Investor Inquiries, please contact:

Maxim Jacobs, CFA

Vice President, Investor Relations and Corporate Communications

Mind Medicine (MindMed) Inc.

ir@mindmed.co

media@mindmed.co

Source: Mind Medicine

