

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): March 7, 2024**

**Mind Medicine (MindMed) Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**British Columbia, Canada**  
(State or Other Jurisdiction  
of Incorporation)

**001-40360**  
(Commission  
File Number)

**98-1582538**  
(IRS Employer  
Identification No.)

**One World Trade Center, Suite 8500**  
**New York, New York**  
(Address of Principal Executive Offices)

**10007**  
(Zip Code)

**Registrant's telephone number, including area code: (212) 220-6633**

**Not Applicable**  
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Shares, no par value per share	MNMD	The Nasdaq Stock Market LLC

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure**

On March 7, 2024, Mind Medicine (MindMed) Inc. (the “Company”) issued a press release announcing that the U.S. Food & Drug Administration has granted breakthrough designation to the Company’s MM120 (lysergide d-tartrate) program for the treatment of generalized anxiety disorder (“GAD”) and that the Company’s Phase 2b trial of MM120 in GAD met its key secondary endpoint, demonstrating statistically significant durability of effect through Week 12. A copy of the press release is attached hereto as Exhibit 99.1.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission, or the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 8.01 Other Events.**

On March 7, 2024, the Company delivered written notice to Cantor Fitzgerald & Co. and Oppenheimer & Co. Inc. (the “Agents”) that it was suspending and terminating the prospectus, dated May 16, 2022 (the “ATM Prospectus”), relating to up to \$100,000,000 of the Company’s common shares that may be issued and sold pursuant to the Controlled Equity Offering<sup>SM</sup> Sales Agreement, dated as of May 3, 2022, by and between the Company and the Agents (the “Sales Agreement”). The Company will not make any sales of its common shares pursuant to the Sales Agreement, unless and until a new prospectus, prospectus supplement or registration statement is filed. Other than the termination of the ATM Prospectus, the Sales Agreement remains in full force and effect.

On March 7, 2024, the Company also posted an updated investor presentation on its website. A copy of the presentation is filed herewith as Exhibit 99.2 and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits.**

<u>Exhibit</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated March 7, 2024</a>
99.2	<a href="#">Investor Presentation, dated March 7, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 7, 2024

**Mind Medicine (MindMed) Inc.**

By: /s/ Robert Barrow

Name: Robert Barrow

Title: Chief Executive Officer

THURSDAY MARCH 7, 2023, 6:00 AM EST

**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.



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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.

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### **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](http://mindmed.co)) or on [clinicaltrials.gov](https://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<sub>2A</sub>]) 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

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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](http://www.sedar.com) and with the U.S. Securities and Exchange Commission on EDGAR at [www.sec.gov](http://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.

For Media Inquiries, please contact: [media@mindmed.co](mailto:media@mindmed.co)

For Investor Inquiries, please contact: [ir@mindmed.co](mailto:ir@mindmed.co)

Source: Mind Medicine (MindMed) Inc.



**MindMed**

**MM120 for GAD**  
**Investor Presentation**

March 2024

# Disclaimer

This presentation (the "Presentation") has been prepared by Mind Medicine (MindMed) Inc. ("MindMed", the "Company", "we", "our" or "us) solely for informational purposes. None of MindMed, its affiliates or any of their respective employees, directors, officers, contractors, advisors, members, successors, representatives or agents makes any representation or warranty as to the accuracy or completeness of any information contained in this Presentation and shall have no liability for any representations (expressed or implied) contained in, or for any omissions from, this Presentation. This Presentation does not constitute an offering of, or a solicitation of an offer to purchase, securities of MindMed and under no circumstances is it to be construed as a prospectus or advertisement or public offering of securities. Any trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of the products or services of MindMed. Any amounts are in USD unless otherwise noted. MindMed's securities have not been approved or disapproved by the Securities and Exchange Commission (the "SEC") or by any state, provincial or other securities regulatory authority, nor has the SEC or any state, provincial or other securities regulatory authority passed on the accuracy or adequacy of this Presentation. Any representation to the contrary is a criminal offense.

## Cautionary Note Regarding Forward-Looking Statements

This Presentation contains, and our officers and representatives may from time to time make, "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Forward-looking statements can often, but not always, be identified by words such as "plans", "expects", "is expected", "budget", "scheduled", "estimates", "forecasts", "intends", "anticipates", "will", "projects", or "believes" or variations (including negative variations) of such words and phrases, or statements that certain actions, events, results or conditions "may", "could", "would", "might" or "will" be taken, occur or be achieved, and similar references to future periods. Except for statements of historical fact, examples of forward-looking statements include, among others, statements pertaining to: the development and commercialization of any medicine or treatment, or the efficacy of either of the foregoing, the success and timing of our development activities; the success and timing of our planned clinical trials; our ability to meet the milestones set forth herein; the likelihood of success of any clinical trials or of obtaining FDA or other regulatory approvals; our cash runway funding operations through key clinical readouts and into 2026; the likelihood of obtaining patents or the efficacy of such patents once granted and the potential for the markets that MindMed is anticipating to access.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions as of the date of this Presentation. While MindMed considers these assumptions to be reasonable, the assumptions are inherently subject to significant business, social, economic, political, regulatory, competitive and other risks and uncertainties that are difficult to predict and many of which are outside of MindMed's control, and actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to raise capital to complete its plans and fund its studies; the medical and commercial viability of the contemplated medicines and treatments being developed; MindMed's history of negative cash flows; MindMed's limited operating history; incurrence of future losses; 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 throughout the "Risk Factors" sections of MindMed's most recently filed Annual Report on Form 10-K filed with the SEC and in other filings we make in the future with the SEC and the securities regulatory authorities in all provinces and territories of Canada, available under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com).

Any forward-looking statement made by MindMed in this Presentation is based only on information currently available to the Company and speaks only as of the date on which it is made. MindMed undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

## Cautionary Note Regarding Regulatory Matters

The United States federal government regulates drugs through the Controlled Substances Act. MM120 is a proprietary, pharmaceutically optimized form of lysergide D-tartrate and MM402, or R(-)-MDMA, is our proprietary form of the R-enantiomer of MDMA (3,4-methylenedioxymethamphetamine). Lysergide and MDMA are Schedule I substances under the Controlled Substances Act. While the Company is focused on programs using psychedelic or hallucinogenic compounds and non-hallucinogenic derivatives of these compounds, including in its MM120, MM402 and other product candidates, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates. The Company is a neuro-pharmaceutical drug development company and does not deal with psychedelic or hallucinogenic substances except within laboratory and clinical trial settings conducted within approved regulatory frameworks. The Company's products will not be commercialized prior to applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended uses is successfully developed.

## Market and Industry Data

This Presentation includes market and industry data that has been obtained from third party sources, including industry publications. MindMed believes that the industry data is accurate and that the estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although the data is believed to be reliable, MindMed has not independently verified any of the data from third party sources referred to in this Presentation or ascertained the underlying economic assumptions relied upon by such sources. References in this Presentation to research reports or to articles and publications should be not construed as depicting the complete findings of the entire referenced report or article. MindMed does not make any representation as to the accuracy of such information.

## Introductory Remarks

Robert Barrow  
Chief Executive Officer



# We Aim To Be A Global Leader In Brain Health



# MindMed Research & Development Pipeline

Product Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration
<b>Psychiatry Programs</b>						
<b>MM120</b> <i>(Lysergide D-tartrate)</i>	Generalized Anxiety Disorder (GAD) <sup>1</sup>	[Progress bar spanning Preclinical, Phase 1, and Phase 2]				
	Additional Psychiatric Indication <sup>2</sup>	[Progress bar spanning Preclinical and Phase 1]				
<b>MM402</b> <i>(R(-)-MDMA)</i>	Autism Spectrum Disorder (ASD) <sup>1</sup>	[Progress bar spanning Preclinical and Phase 1]				
<b>Early Research &amp; Collaborations</b>						
<b>IITs</b> <i>(UHB collaboration)</i>	Various <sup>1</sup>	[Progress bar spanning Preclinical and Phase 1]				
<b>Early Research</b> <i>(Mindshift collaboration)</i>	Various	[Progress bar in Preclinical]				



1. Full trial details and [clinicaltrials.gov](https://clinicaltrials.gov) links available at [mindmed.co/clinical-digital-trials/](https://mindmed.co/clinical-digital-trials/)  
 2. Study in exploration and/or planning stage.  
 LSD: lysergide; MDMA: 3,4-methylenedioxyamphetamin. IIT: Investigator Initiated Trial (results are not anticipated to be used in our applications for regulatory approval); UHB: University Hospital Basel



# MM-120 Has the Potential to Address a Large Unmet Need in GAD

## Opportunity in Generalized Anxiety Disorder (GAD)

- GAD is the 2nd most common mental disorder among adults<sup>1</sup>, yet there are limited treatment options
- Symptoms may be debilitating and treatment inefficacy leads to incomplete remission and intolerable side effects.



**Potential Best-in-Class Therapy with Novel MOA**

## Large Market Opportunity

~20 million US adults with GAD<sup>1</sup>  
77% moderate to severe<sup>2</sup>

13 million  
receive treatment<sup>1</sup>

6.5 million do not respond  
to first-line treatment<sup>3</sup>

## Significant Need for New Treatments

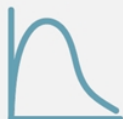
- ▶ **SSRI/SNRIs<sup>1</sup>**: 50% failure rate with often undesirable side effects
- ▶ **Benzodiazepines**: addiction, tolerance risk; generally used in short-term
- ▶ **Buspirone<sup>4</sup>**: poor efficacy
- ▶ **Antipsychotics**: short- and long-term risks; poorly tolerated

## Key Highlights of MM-120 Updates



### Positive 12-Week Durability in Phase 2b Trial of GAD<sup>1</sup>

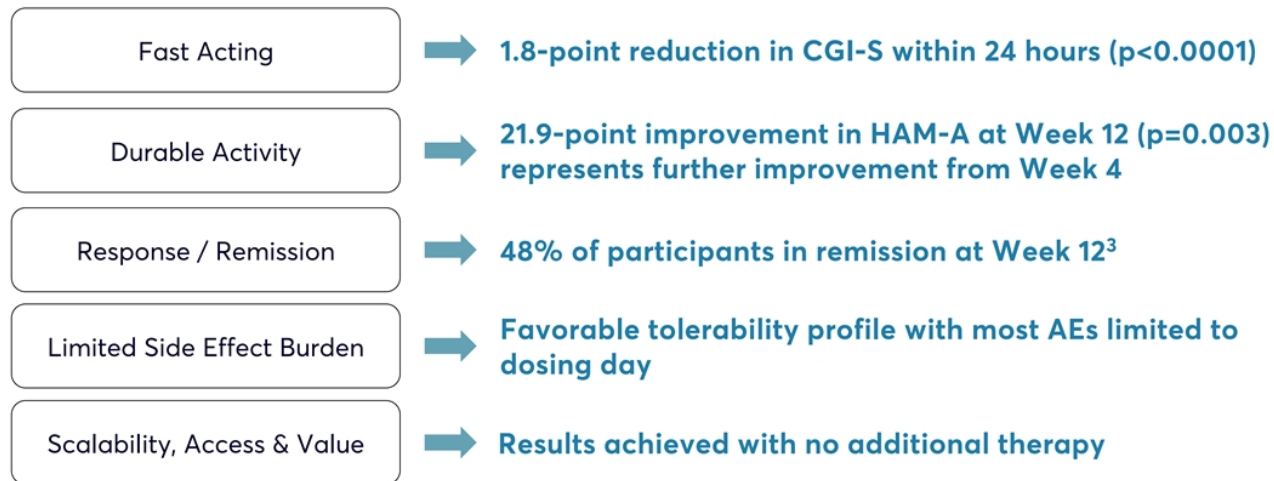
- Primary and secondary endpoints met with statistical significance
- 7.7-point improvement over placebo ( $d=0.81$ ;  $p=0.003$ )
- 48% clinical remission rate at Week 12



### Enhanced Product Profile with MM-120 ODTs<sup>2</sup>

- Differentiated profile observed in PK bridging study
- Rapid absorption, improved bioavailability & greater therapeutic AUC observed

## Results for MM120 in GAD Delivered on Target Product Profile after Single Dose with Significant Improvement in All Endpoints<sup>1,2</sup>



# 12-Week Durability Observed with Effect Size Over Double the Standard of Care<sup>1,3</sup>

## Comparative Effect Sizes in GAD



## Key Highlights of Phase 2b 12 Week Results

- Maximum observed **effect size of 0.81 is more than double the standard of care**<sup>2,3</sup>
- **Rapid and durable clinical response** observed after single administration<sup>3</sup>
- Clinical activity observed with **no psychotherapeutic intervention** beyond study drug

# PK Bridging Study Demonstrates Enhanced Product Profile for MM120 ODTs

## Differentiated Performance of MM120 ODTs



50% faster onset of action<sup>2</sup>



17% improved bioavailability<sup>3</sup>

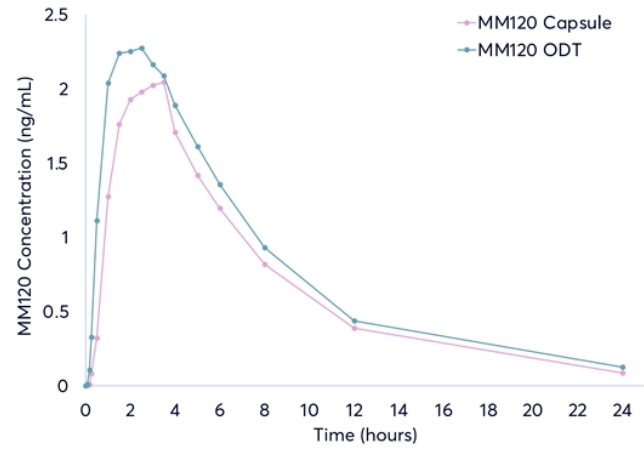


23% increase in AUC at target conc.<sup>4</sup>



Reduced GI side effects<sup>5</sup>

## Comparative PK Profile<sup>1</sup>



**MM120 LSD-D-tartrate**  
for Generalized Anxiety Disorder (GAD)

**Summary of Full Topline Results from Phase 2b Trial**

Daniel R Karlin, MD, MA  
Chief Medical Officer



# Positive 12-Week Topline Results from Phase 2b Study in GAD: Strong Durability of Effect after Single Dose of MM120<sup>1</sup>

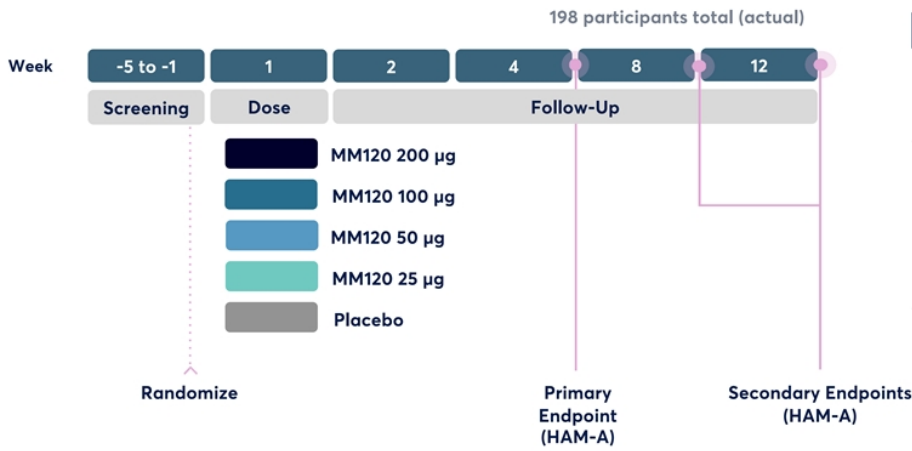
- Met the primary and all secondary endpoints with statistical significance<sup>2</sup>
- MCP-Mod analysis results support dose-response relationship for MM120 in GAD
- Large observed effect size of  $d=0.81$  at 12 weeks is more than double the standard of care<sup>3,4</sup>
  - Durability of at least 3 months after a single dose of MM120 observed
- Statistically and clinically significant 21.9-point improvement in HAM-A score at week 12 ( $p=0.0025$ ) represents further improvement from four-week topline data<sup>3</sup>
  - Rapid and durable clinical activity with continued improvement at week 12
  - 48% clinical remission rate through 12-week observation period<sup>5</sup>
  - Clinically and statistically significant improvements on all analyzed secondary endpoints at week 12<sup>2</sup>
- MM120 was well-tolerated with no related serious adverse events
  - Mostly transient, mild-to-moderate adverse events consistent with drug class and prior studies
  - No drug-related serious adverse event (SAE) and no suicide-related safety signal<sup>6</sup>
- Supports long-term durability of single administration MM120 and we believe further supports advancement of 100  $\mu$ g MM120 into Phase 3 development for GAD

## Phase 2b Trial of MM120 Utilized Standard GAD Design and Endpoints and was Aligned with FDA Draft Guidance for Drug Class<sup>1</sup>

- **Standard GAD study design with endpoints that have supported registration for approved drugs**
- **Randomized, double-blind, placebo-controlled, 12-week trial**
  - Single administration of MM-120 or placebo
  - No psychotherapeutic intervention
  - Trial design closely aligned with subsequently issued FDA 2023 Draft Guidance<sup>2</sup>
  - Patients washed out of anxiety pharmacotherapy prior to randomization
- **Enrolled 198 patients with GAD**
- **Five-arm dose optimization design with 1:1:1:1:1 randomization**
- **Primary endpoint: change in Hamilton Anxiety Scale (HAM-A) at week 4**
  - Assessed by central rater blinded to treatment assignment and visit number



# Phase 2b Trial Schematic<sup>1</sup>



## Study MMED008 | MM120 for GAD

A Phase 2b Dose Optimization Study of a Single Dose of MM120 in Generalized Anxiety Disorder

### KEY ENTRY CRITERIA

- Men and Women
- Ages 18-74
- Diagnosis of GAD
- HAM-A  $\geq$  20

### ADDITIONAL ENDPOINTS

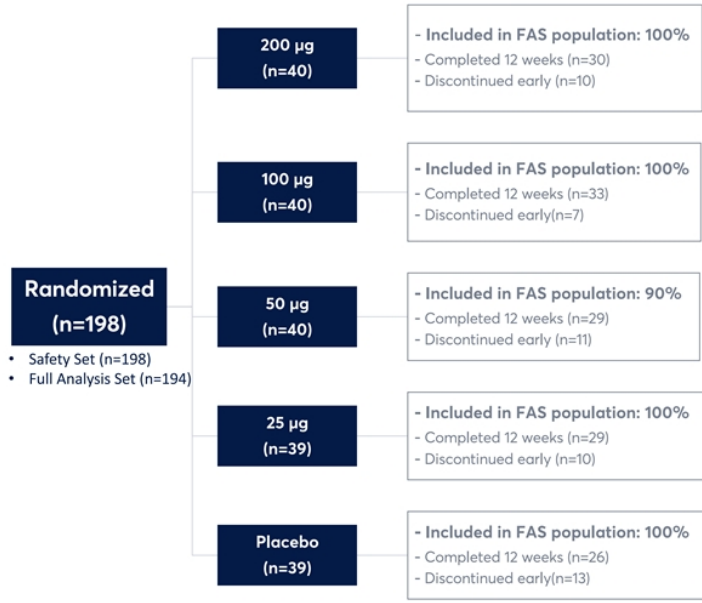
- MADRS
- CGI-S / I
- PGI-S / C
- SDS
- EQ-5D-5L
- PSQI
- ASEX

# Phase 2b Treatment Paradigm: Standalone Drug Effects with No Psychotherapeutic Intervention<sup>1</sup>

- Dosing session monitors (DSMs) in the room provide no psychotherapeutic intervention
- Delivery protocol consistent with 2023 FDA Draft Guidance<sup>2</sup>
- No changes planned to drug delivery between Phase 2 and Phase 3

	Pre-treatment	During treatment	Post-treatment
<b>Patient Journey in MMED008</b>	<ul style="list-style-type: none"> <li>✓ Comprehensive informed consent process</li> <li>✓ Eligibility evaluation</li> </ul>	<ul style="list-style-type: none"> <li>✓ Continuous monitoring by DSMs</li> <li>✓ Music, eye shades, reading, writing</li> <li>✓ Concludes when discharge criteria met</li> </ul>	<ul style="list-style-type: none"> <li>✓ Follow-up visits for assessment only</li> </ul>
<b>Not Part of Patient Journey in MMED008</b>	<ul style="list-style-type: none"> <li>x No "preparation"</li> <li>x Pre-treatment activities consisted of a comprehensive informed consent process</li> </ul>	<ul style="list-style-type: none"> <li>x No "assisted therapy"</li> <li>x No psychotherapy and no therapeutic intervention beyond study drug</li> </ul>	<ul style="list-style-type: none"> <li>x No "integration"</li> <li>x No ongoing therapeutic engagement as part of clinical trial activities</li> </ul>

# Participant Disposition Aligned with Historical Expectations<sup>1</sup>



**79% 12-week completion rate**  
in high dose groups<sup>2</sup> despite need for follow-up visits with no additional treatment

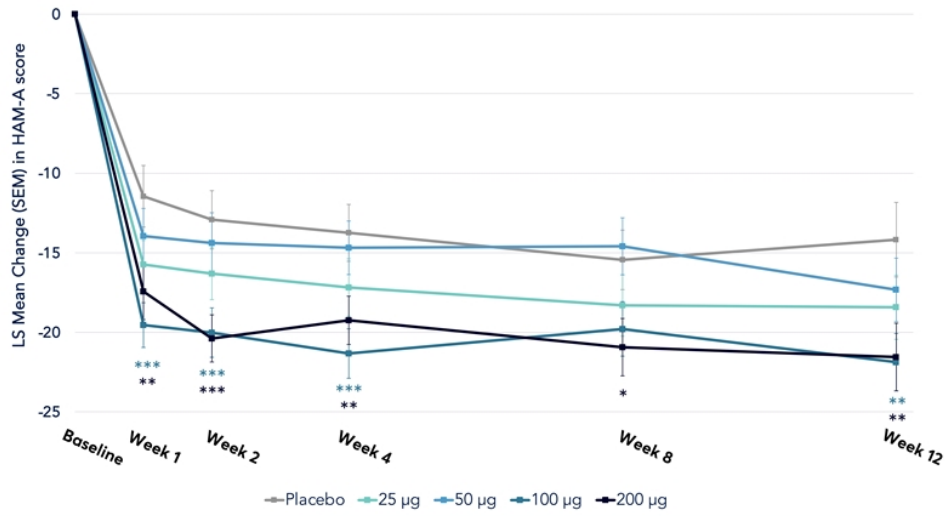
**74% 12-week completion rate**  
of all randomized participants which is consistent with other studies in drug class

## Participant Demographics and Baseline Characteristics Generally Balanced Across Groups<sup>1</sup>

Demographic (n=194)	MM120				Placebo (n=39)
	25 µg (n=39)	50 µg (n=36)	100 µg (n=40)	200 µg (n=40)	
Mean age (years)	38.0	45.3	42.7	42.1	38.7
Sex, female (%)	51.3%	55.6%	40.0%	70.0%	66.7%
Race (% white)	84.6%	80.6%	90.0%	82.5%	76.9%
Baseline HAM-A score	30.2	30.3	29.3	31.0	30.3
Baseline CGI-S score	4.9	4.9	4.8	5.1	4.9

# Statistically and Clinically Significant Reductions in HAM-A Score Continued at Week 12<sup>1,2</sup>

## HAM-A Change from Baseline



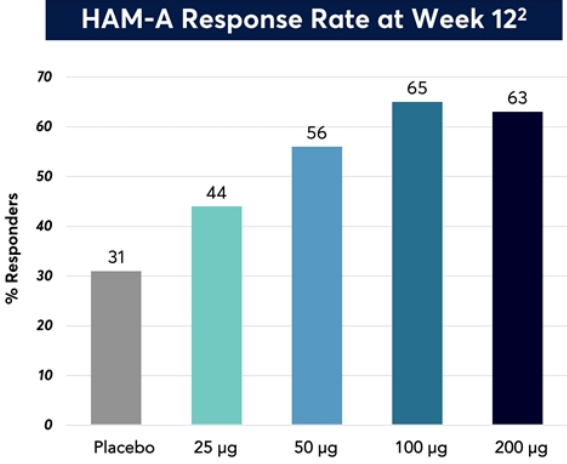
- Change from Baseline<sup>2</sup>**
- Week 4: -21.3 points
  - Week 12: -21.9 points
- Improvement over Placebo<sup>2</sup>**
- Week 4: -7.6 pts, p=0.0004
  - Week 12: -7.7 pts, p=0.003

\*\*p<0.05  
 \*\*\*p<0.001

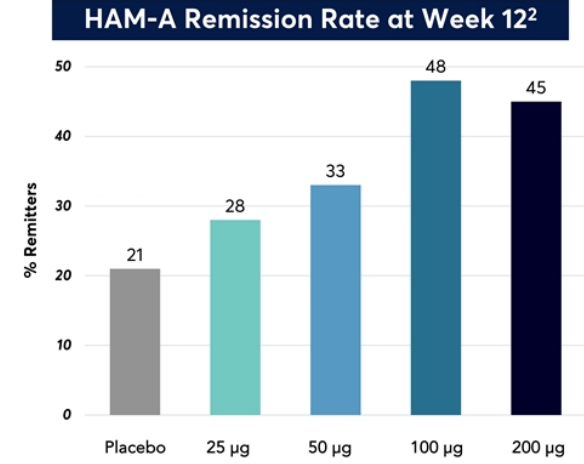


1. Source: Study MMED008 internal study documents and calculations. Full analysis set population.  
 2. Based on 100 µg dose group.  
 µg: microgram; HAM-A: Hamilton Anxiety Rating Scale; NOTE: Significance achieved despite study not being powered for these pairwise comparisons.

# Continued Response and Remission through Week 12 with 65% Clinical Responder Rate and 48% Clinical Remission Rate<sup>1</sup>



p-values not calculated

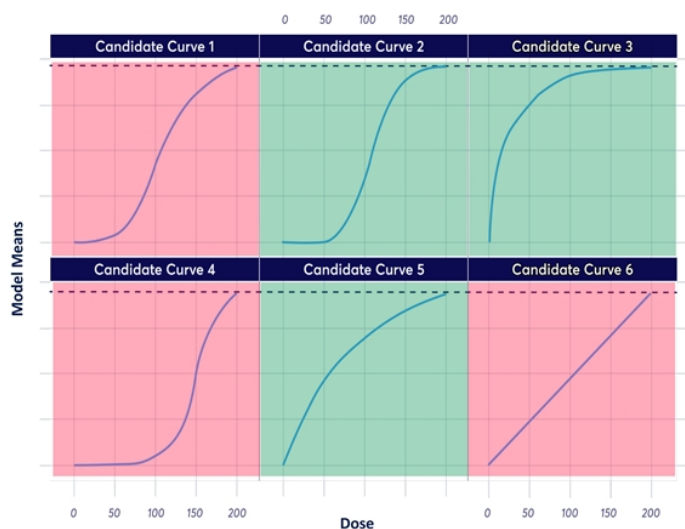


p-values not calculated



1. Source: Study MMED008 internal study documents and calculations. Full analysis set population.  
 2. Response is defined as a 50% or greater improvement on HAM-A score; Remission is defined as a HAM-A score of  $\leq 7$ .  
 µg: microgram; HAM-A: Hamilton Anxiety Rating Scale

# Primary & Key Secondary Analysis (MCP-Mod) Support Dose Response Relationship for MM120 in GAD<sup>1</sup>



## Key Takeaways from MCP-Mod Analysis<sup>2</sup>

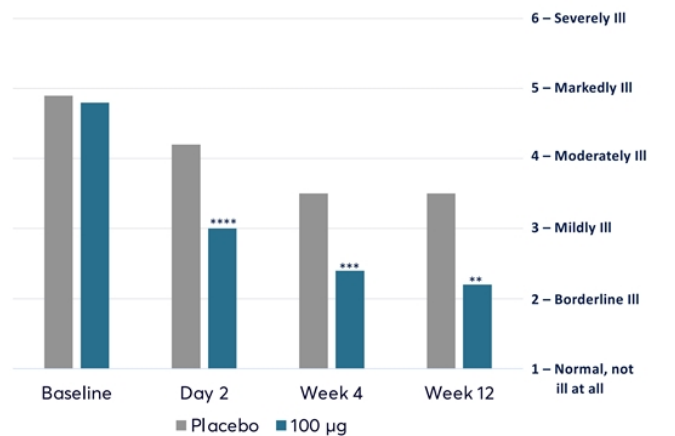
- Statistically significant dose response relationship with multiple model fits
- Supports dose selection of 100 µg for subsequent studies in GAD
- Pre-specified model estimates and observed responses drive dose selection for Phase 3 studies

# Rapid and Sustained Improvements in Clinical Global Impressions – Severity (CGI-S) Starting on Day 2 and Continuing through Week 12<sup>1</sup>

## CGI-S Improvement in 100 µg Group

- Statistically and clinically significant improvement by Day 2 and maintained through Week 12
- Greater than 2-unit improvement in CGI-S score through Week 12
- Participants on average only borderline-to-mildly ill at Week 12

## CGI-S Scores at Week 12<sup>2</sup>



\*p<0.05  
 \*\*p≤0.01  
 \*\*\*p≤0.001  
 \*\*\*\*p≤0.0001

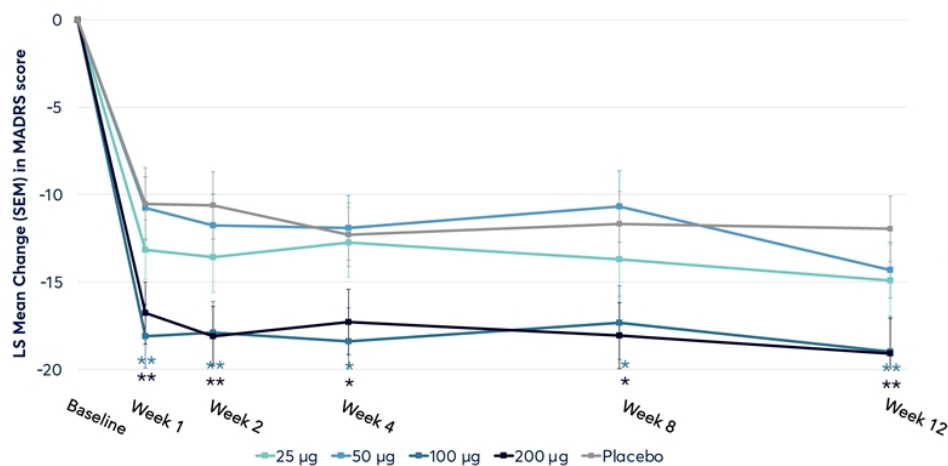


1. Source: Study MMED008 internal study documents and calculations. Full analysis set population.  
 2. Significance achieved despite study not being powered for these pairwise comparisons.  
 µg: microgram; CGI-S: Clinical Global Impressions - Severity



# Statistically and Clinically Significant Reductions in Comorbid Depression (MADRS) at All Timepoints through Week 12<sup>1,2</sup>

MADRS Change from Baseline<sup>3</sup>



### Change from Baseline<sup>2,3</sup>

- Week 4: -18.1 points
- Week 12: -18.7 points

### Improvement over Placebo<sup>2,3</sup>

- Week 4: -5.7 points,  $p < 0.05$
- Week 12: -6.4 points,  $p < 0.01$

\* $p < 0.05$   
\*\* $p \leq 0.01$



1. Source: MindMed internal study documents and calculations. Full analysis set population.  
2. Based on 100 µg dose group.  
3. Significance achieved despite study not being powered for these pairwise comparisons. Based on observed MADRS score at each timepoint.  
µg: microgram; MADRS: Montgomery-Åsberg Depression Rating Scale

# MM120 was Well-tolerated with Mostly Transient, Mild-to-Moderate Adverse Events Consistent with Drug Class Expectations<sup>1</sup>

## Favorable tolerability profile

- Virtually all AEs (99%) were mild-to-moderate in severity
- Minimal (2.5%) TEAEs led to study withdrawal
- No drug-related serious adverse events (SAEs)<sup>2</sup>

## No SAEs related to study drug

- Only SAE was in 50 µg dose group and deemed unrelated
- Adverse event profile consistent with historical studies and drug class

## No suicidal behavior or suicidality signal<sup>3</sup>

- No suicidal or self-injurious behavior
- ≤ 2 participant per arm reported suicidal ideation during the study
- No indication of increased suicidality or suicide-related risk

## Most Common ( $\geq 10\%$ ) TEAEs in High-Dose Groups Demonstrate Favorable Tolerability Profile<sup>1,2</sup>

Preferred Term Subjects (%) with AE	MM120								Placebo (n=39)	
	25 µg (n=39)		50 µg (n=40)		100 µg (n=40)		200 µg (n=40)		DD	AFT
	DD	AFT	DD	AFT	DD	AFT	DD	AFT		
Illusion	12 (31)	1 (2.6)	18 (45)	1 (2.5)	24 (60)	1 (2.5)	30 (75)	–	3 (7.7)	–
Nausea	3 (7.7)	–	11 (28)	–	16 (40)	1 (2.5)	24 (60)	2 (5.0)	1 (2.6)	2 (5.1)
Headache	4 (10)	2 (5.1)	9 (23)	2 (5.0)	10 (25)	4 (10)	10 (25)	1 (2.5)	8 (21)	1 (2.6)
Hallucination, visual	6 (15)	1 (2.6)	9 (23)	–	9 (23)	–	6 (15)	–	1 (2.6)	–
Euphoric mood	2 (5.1)	–	5 (13)	–	11 (28)	–	6 (15)	–	1 (2.6)	–
Anxiety	1 (2.6)	3 (7.7)	3 (7.5)	3 (7.5)	4 (10)	–	5 (13)	1 (2.5)	–	2 (5.1)
Mydriasis	1 (2.6)	–	7 (18)	–	8 (20)	–	4 (10)	–	1 (2.6)	–
Hyperhidrosis	1 (2.6)	–	4 (10)	–	9 (23)	–	5 (13)	–	–	–
Paraesthesia	2 (5.1)	–	2 (5.0)	–	2 (5.0)	–	8 (20)	–	2 (5.1)	1 (2.6)
Blood pressure increased	3 (7.7)	–	5 (13)	–	4 (10)	–	4 (10)	–	–	–
Dizziness	3 (7.7)	–	2 (5.0)	–	3 (7.5)	–	5 (13)	–	1 (2.6)	–
Tremor	–	–	3 (7.5)	–	2 (5.0)	1 (2.5)	8 (20)	–	–	–
Thinking abnormal	1 (2.6)	–	2 (5.0)	–	4 (10)	1 (2.5)	5 (13)	–	–	–
Pseudohallucination	–	–	3 (7.5)	–	3 (7.5)	–	4 (10)	–	–	–
Feeling abnormal	1 (2.6)	–	2 (5.0)	–	–	–	–	4 (10)	1 (2.6)	1 (2.6)
COVID-19	–	1 (2.6)	–	2 (5.0)	–	1 (2.5)	–	4 (10)	–	–

1. Source: Study MMED008 internal study documents and calculations. Safety population.
  2. High dose groups include 100 and 200 µg dose groups.
- AFT: After Dosing Day; DD: Dosing Day; TEAE: Treatment-emergent adverse event.

**MM120 LSD-D-tartrate**  
for Generalized Anxiety Disorder (GAD)

**MM120 ODT PK Bridging Study**

Daniel R Karlin, MD, MA  
Chief Medical Officer



# PK Bridging Study Demonstrates Enhanced Product Profile for MM120 ODTs

## Differentiated Performance of MM120 ODTs



50% faster onset of action<sup>2</sup>



17% improved bioavailability<sup>3</sup>

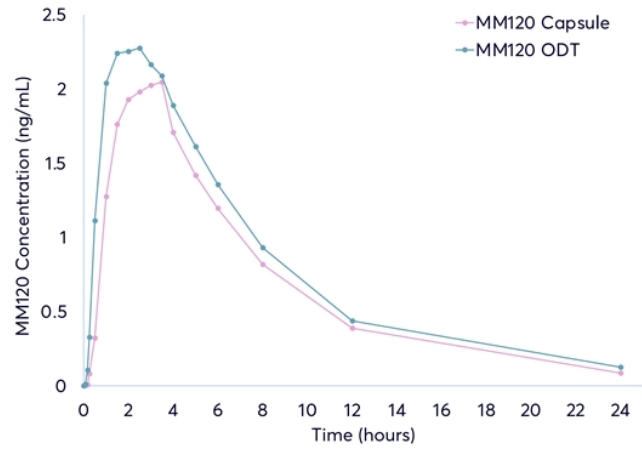


23% increase in AUC at target conc.<sup>4</sup>

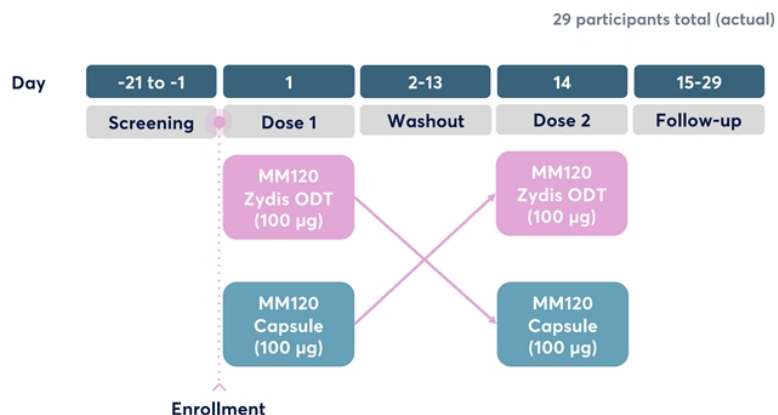


Reduced GI side effects<sup>5</sup>

## Comparative PK Profile<sup>1</sup>



# MM120 ODT PK Bridging Study Schematic<sup>1</sup>



## Study MM120-101 | ODT-PK Bridging

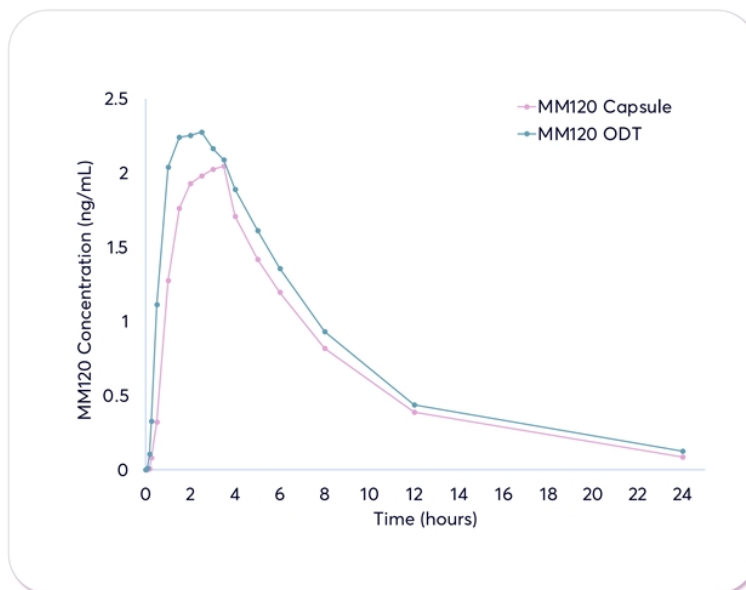
A Phase 1, Open-label Study to Compare the Pharmacokinetics of Two Formulations of MM120 in Healthy Volunteers

### ENTRY CRITERIA

- Men and Women
- Ages 18-55
- Healthy volunteers
- No prohibited medications

# Comparative PK of MM120 ODT vs Capsule Demonstrates Favorable Profile of MM120 ODTs<sup>1</sup>

PK Parameter <sup>1</sup>	MM120 Capsule	MM120 ODT
T <sub>max</sub> (hr)	2.25	2.0
C <sub>max</sub> (ng/mL)	2.63	2.68
AUC <sub>0-∞</sub> (ng*hr/mL)	15.7	18.7
AUC <sub>&gt;1ng/mL</sub> (ng*hr/mL)	9.7	12.0



# MM120 ODT Demonstrates Faster Absorption and Shorter Time to Reach Target Concentrations

## Differentiated PK Profile of MM120 ODTs<sup>1</sup>



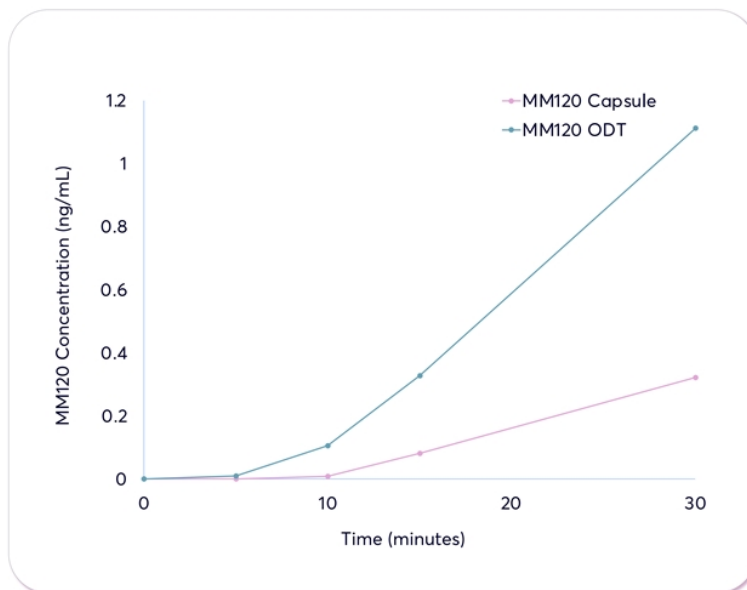
50% faster onset of action<sup>2</sup>



17% improved bioavailability<sup>3</sup>



23% increased AUC above target conc.<sup>4</sup>





# MM120 ODT Demonstrates Improved Bioavailability<sup>1</sup>

## Differentiated PK Profile of MM120 ODTs<sup>1</sup>



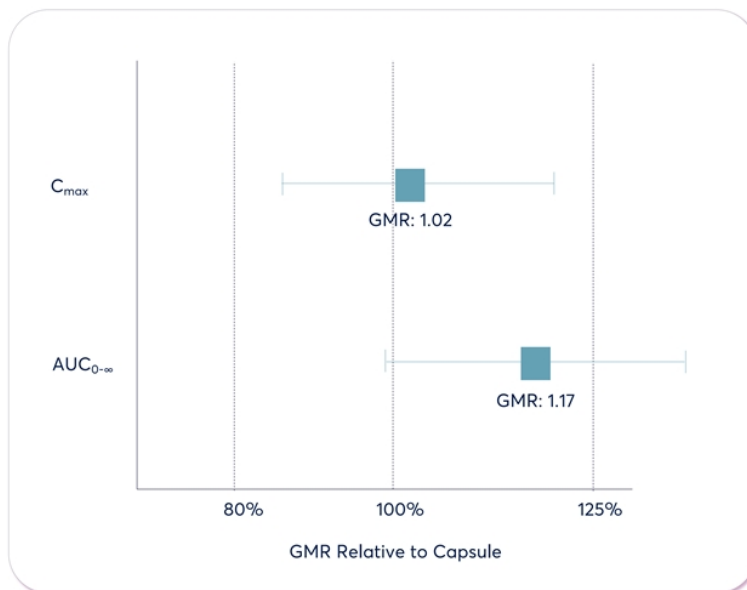
50% faster onset of action<sup>2</sup>



17% improved bioavailability<sup>3</sup>



23% increased AUC above target conc.<sup>4</sup>



# MM120 ODT Achieves Increased AUC Above Target Concentration

## Differentiated PK Profile of MM120 ODTs<sup>1</sup>



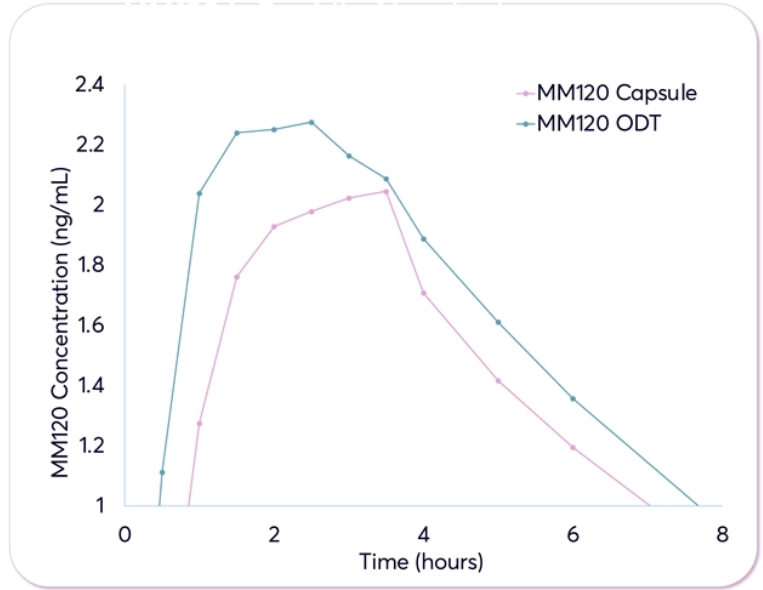
50% faster onset of action<sup>2</sup>



17% improved bioavailability<sup>3</sup>



23% increased AUC above target conc.<sup>4</sup>



**Summary Comments for  
MM120 Development Plan**

**Robert Barrow**  
Chief Executive Officer



## Multiple Studies Support Phase 3 Development of MM120

- **Achieved goals of Phase 2 development<sup>1</sup>**
  - Characterized dose-response to inform dose selection in GAD
  - Large, statistically significant and clinically meaningful effect in GAD
  - Rapid and durable therapeutic benefits on validated endpoint
  - Standalone drug effect in absence of psychotherapeutic intervention
- **Multiple double-blind, placebo-controlled studies supporting activity of MM120**
  - Phase 2b randomized, placebo-controlled dose optimization trial in GAD (Study MMED008)
  - One prior modern, randomized, placebo-controlled IIT of lysergide in anxiety disorders
  - Over twenty legacy studies of lysergide in anxiety and other neurotic disorders
- **Phase 2b data supports dose selection and advancement into Phase 3 development**

## MM120 Development Pathway

- **Two Phase 3 pivotal clinical trials in planning<sup>1</sup>**
  - 12-week randomized, placebo-controlled primary efficacy study design
  - Open-label extension to establish retreatment parameters
  - Expect to initiate Phase 3 development in the second half of 2024
- **Key design elements expected to be consistent between Phase 2b and Phase 3 studies**
  - Hamilton Anxiety Scale (HAM-A) at week 4 expected primary endpoint
  - Limited changes to key inclusion/exclusion criteria
  - No planned change in dosing session monitoring protocol

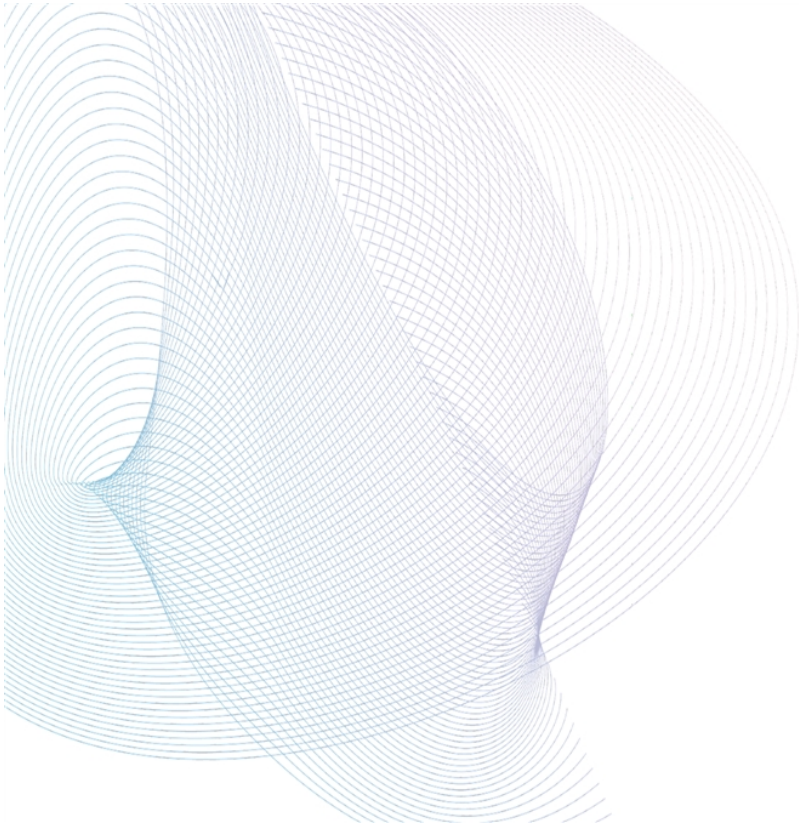
# Next Steps and Anticipated Milestones for MM120 and Pipeline Programs

Q1 2024	Q2 2024	Q3 2024	Q4 2024
<p><b>MM120 GAD</b> Phase 2b / 12-wk Topline</p>	<p><b>MM120 GAD</b> Full data presentation at scientific meeting</p>		
<p><b>MM120 GAD</b> Zydis ODT PK Bridging Data</p>			
<p><b>MM120 GAD</b> End-of-Phase-2 meeting w/FDA</p>		<p><b>MM120 GAD</b> Phase 3 initiation</p>	
		<p><b>MM120</b> Evaluate additional clinical indication(s) for MM120</p>	
<p><b>MM402/R-MDMA</b> Phase 1 IIT (UHB-sponsored) Topline</p>			



# MindMed

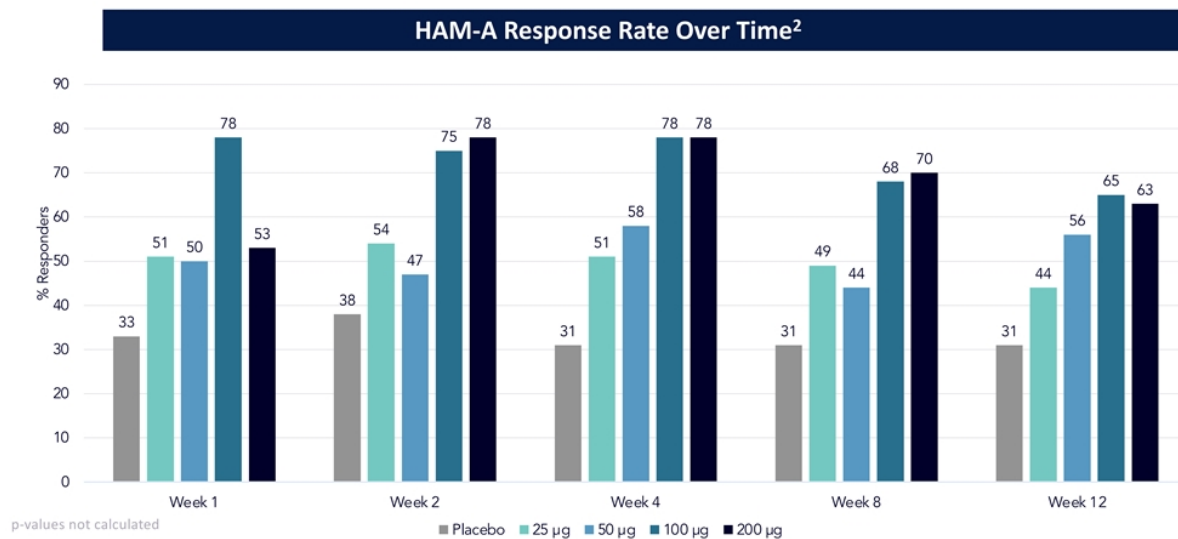
## Q&A



## Appendix

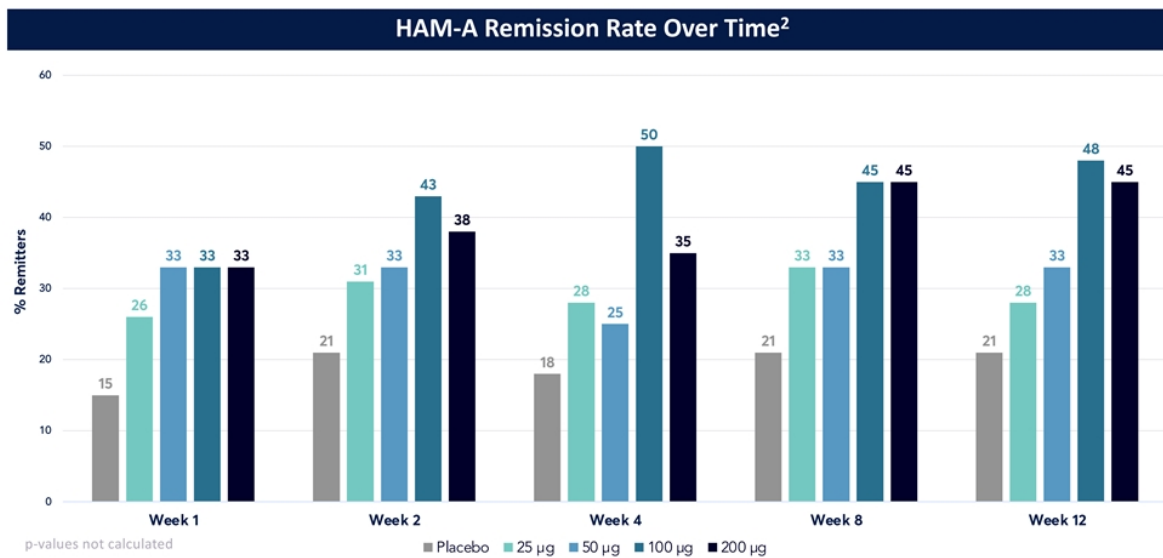


# 65% HAM-A Response Rate (HAM-A) Achieved at Week 12<sup>1,3</sup>



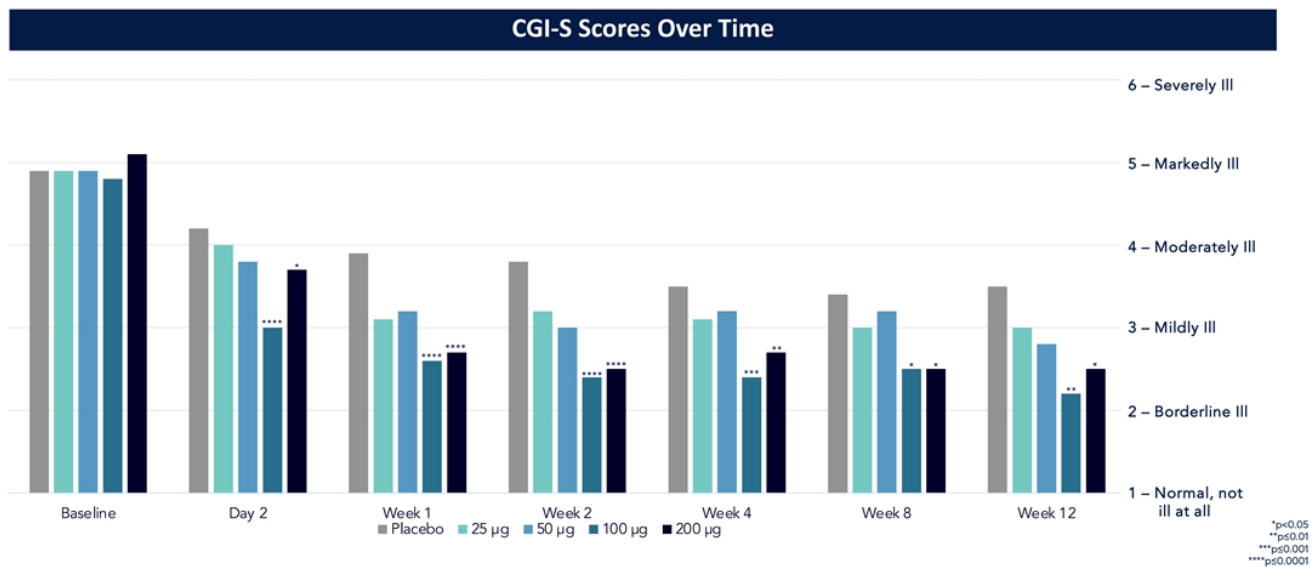
1. Source: Study MMED008 internal study documents and calculations. Full analysis set population.  
 2. Response is defined as a 50% or greater improvement on HAM-A score.  
 3. Based on 100 µg dose group.  
 µg: microgram; HAM-A: Hamilton Anxiety Rating Scale.

# 48% Remission Rate (HAM-A) Achieved through Week 12<sup>1,3</sup>



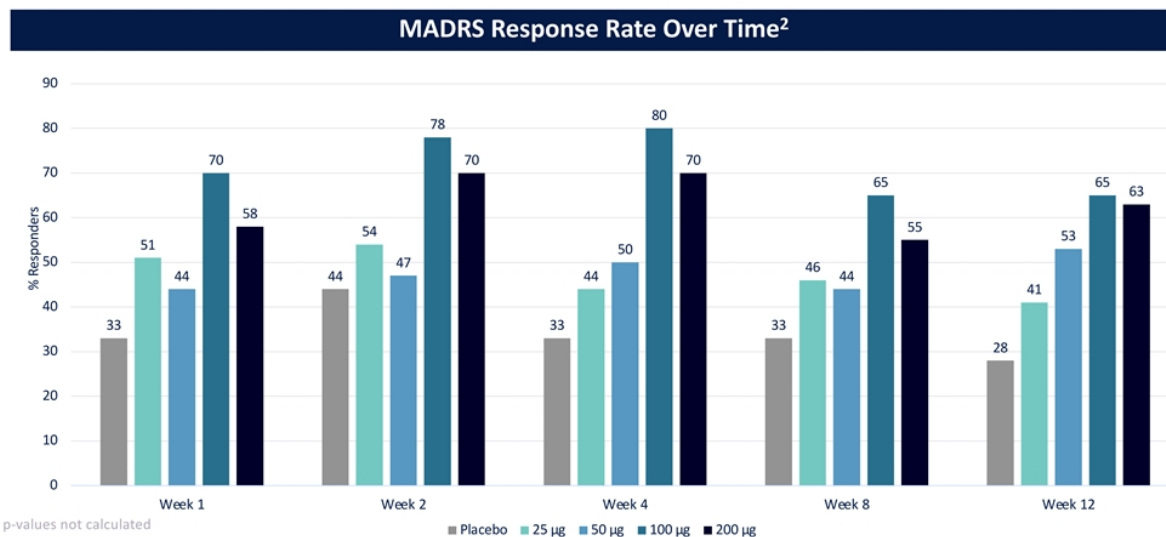
1. Source: Study MMED008 internal study documents and calculations. Full analysis set population.  
2. Remission is defined as a HAM-A score of  $\leq 7$ .  
3. Based on 100 µg dose group.  
µg: microgram; HAM-A: Hamilton Anxiety Rating Scale.

# Statistically Significant Improvement in Clinical Global Impressions – Severity (CGI-S) Score Achieved by Day 2 and Sustained through Week 12<sup>1,2</sup>



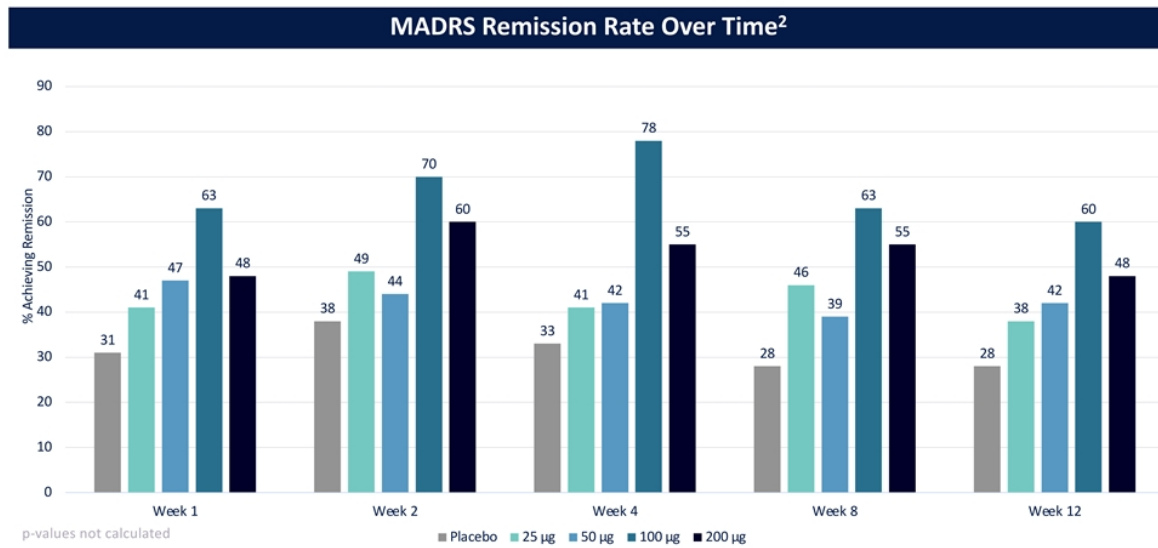
1. Source: Study MMED008 internal study documents and calculations. Full analysis set population.  
 2. Based on 100 µg dose group.  
 µg: microgram; CGI-S: Clinical Global Impressions – Severity

# 65% Response Rate for Comorbid Depression Symptoms (MADRS) Achieved through Week 12<sup>1,3</sup>



1. Source: Study MMED008 internal study documents and calculations. Full analysis set population.  
 2. Response is defined as a 50% or greater improvement on MADRS score.  
 3. Based on 100 µg dose group.  
 µg: microgram; MADRS: Montgomery-Åsberg Depression Rating Scale

# 60% Remission Rate from Comorbid Depression Symptoms (MADRS) Achieved through Week 12<sup>1,3</sup>



# Most Common ( $\geq 10\%$ ) TEAEs Across All Groups<sup>1</sup>

MM120 was well tolerated across all dose groups with mostly transient, mild to moderate adverse events

Preferred Term Subjects (%) with AE	MM120								Placebo (n=39)	
	25 µg (n=39)		50 µg (n=40)		100 µg (n=40)		200 µg (n=40)		DD	AFT
	DD	AFT	DD	AFT	DD	AFT	DD	AFT		
Illusion	12 (31)	1 (2.6)	18 (45)	1 (2.5)	24 (60)	1 (2.5)	30 (75)	–	3 (7.7)	–
Nausea	3 (7.7)	–	11 (28)	–	16 (40)	1 (2.5)	24 (60)	2 (5.0)	1 (2.6)	2 (5.1)
Headache	4 (10)	2 (5.1)	9 (23)	2 (5.0)	10 (25)	4 (10)	10 (25)	1 (2.5)	8 (21)	1 (2.6)
Hallucination, visual	6 (15)	1 (2.6)	9 (23)	–	9 (23)	–	6 (15)	–	1 (2.6)	–
Euphoric mood	2 (5.1)	–	5 (13)	–	11 (28)	–	6 (15)	–	1 (2.6)	–
Anxiety	1 (2.6)	3 (7.7)	3 (7.5)	3 (7.5)	4 (10)	–	5 (13)	1 (2.5)	–	2 (5.1)
Mydriasis	1 (2.6)	–	7 (18)	–	8 (20)	–	4 (10)	–	1 (2.6)	–
Hyperhidrosis	1 (2.6)	–	4 (10)	–	9 (23)	–	5 (13)	–	–	–
Fatigue	2 (5.1)	–	6 (15)	2 (5.0)	3 (7.5)	1 (2.5)	3 (7.5)	1 (2.5)	–	1 (2.6)
Paraesthesia	2 (5.1)	–	2 (5.0)	–	2 (5.0)	–	8 (20)	–	2 (5.1)	1 (2.6)
Blood pressure increased	3 (7.7)	–	5 (13)	–	4 (10)	–	4 (10)	–	–	–
Dizziness	3 (7.7)	–	2 (5.0)	–	3 (7.5)	–	5 (13)	–	1 (2.6)	–
Tremor	–	–	3 (7.5)	–	2 (5.0)	1 (2.5)	8 (20)	–	–	–
Thinking abnormal	1 (2.6)	–	2 (5.0)	–	4 (10)	1 (2.5)	5 (13)	–	–	–

## Most Common ( $\geq 10\%$ ) TEAEs Across All Groups (cont)<sup>1</sup>

MM120 was well tolerated across all dose groups with mostly transient, mild to moderate adverse events

Preferred Term Subjects (%) with AE	MM120								Placebo (n=39)	
	25 µg (n=39)		50 µg (n=40)		100 µg (n=40)		200 µg (n=40)		DD	AFT
	DD	AFT	DD	AFT	DD	AFT	DD	AFT		
Balance disorder	–	–	4 (10)	–	3 (7.5)	–	2 (5.0)	–	1 (2.6)	–
Pseudohallucination	–	–	3 (7.5)	–	3 (7.5)	–	4 (10)	–	–	–
Vomiting	–	–	2 (5.0)	–	2 (5.0)	–	5 (13)	–	–	–
Disturbance in attention	1 (2.6)	–	5 (13)	1 (2.5)	–	1 (2.5)	–	–	–	–
Feeling abnormal	1 (2.6)	–	2 (5.0)	–	–	–	–	4 (10)	1 (2.6)	1 (2.6)
COVID-19	–	1 (2.6)	–	2 (5.0)	–	1 (2.5)	–	4 (10)	–	–