



MindMed

PRESS RELEASE

# MindMed Reports Topline Data From Phase 1 Trial of MM- 110 in Development for the Treatment of Opioid Withdrawal



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– Positive safety and tolerability results support the advancement of MM-110 and guide the Phase 2a dose design in individuals undergoing supervised opioid withdrawal –

● – Phase 2a trial remains on track to initiate  
T in Q2 2022 –

NEW YORK, May 19, 2022 — **Mind  
Medicine (MindMed) Inc** (NASDAQ:  
MNMD), (NEO: MMED), (the "Company"  
or "MindMed"), a clinical stage  
biopharmaceutical company  
developing novel products to treat brain  
health disorders, today announced

topline results from the Phase 1 placebo-controlled trial designed to assess the safety, tolerability, pharmacokinetics and neurocognitive effects of MM-110 in 108 healthy volunteers.



The results showed favorable safety and tolerability, support the advancement of MM-110, and have guided the Phase 2a dose, schedule, and design in individuals undergoing supervised opioid withdrawal. MM-110 (also known as zolunicant HCl or 18-MC) is an  $\alpha 3\beta 4$  nicotinic cholinergic receptor antagonist and non-hallucinogenic proprietary congener of ibogaine.

"As there is a major unmet need to address the ongoing and ever-growing opioid crisis, we are very pleased with the results from our Phase 1 trial, which underscore the potential clinical utility of MM-110 to safely mitigate symptoms of opioid withdrawal," said Daniel R



Karlin, MD MA, Chief Medical Officer of MindMed. "These data build on extensive pharmacology and toxicology studies, as well as encouraging results from preclinical studies that showed reductions in translational markers of opioid withdrawal and multi-day reductions in opioid self-administration following a single-dose administration of MM-110. Together, the data

generated to date support our clinic's development program and bring us a step closer to potentially providing an effective treatment solution with an optimized dosing schedule for withdrawal management. We look forward to leveraging these findings in the upcoming Phase 2a, gated two-part study, which will provide an opportunity for early signs of efficacy and inform the randomized proof-of-concept trial. The Phase 2a trial remains on track to initiate in the second quarter of 2022."

A total of 72 participants received up to 325 mg of MM-110 (n=51) twice on a single day or placebo (n=21), and 36

participants were administered up to 90mg of MM-110 (n=26) twice daily seven days or placebo (n=10). The topline results and observations include the following:

**MM-110 was well-tolerated** up to 500mg per day in the single ascending dose (SAD) arm and 60 mg per day for seven days in the multiple-ascending dose (MAD) arm of the trial.

**A linear pharmacokinetic profile was maintained** across the tested doses and frequencies.

**Observed clinical effects** demonstrated alignment with potent CNS engagement.

**No serious adverse events were reported.**

Treatment emergent adverse events were mild or moderate in severity and resolved without sequelae.

**Clinical laboratory parameters and electrocardiograms** were also assessed with no

findings of clinical concern across the administered dose ranges.

**Next steps:** Consistent with the Phase 1 trial and aligned with the preclinical data, an every-other-day dose regimen is planned for the Phase 2a trial. This dose schedule offers the potential to be a better option than existing treatments for supervised opioid withdrawal.

## About the Phase 1 Trial Design



The Phase 1 single and multiple-ascending dose trial conducted at a single clinical research site in Perth, Australia, evaluated the safety, tolerability, pharmacokinetics, and effects on the neurocognitive activity of MM-110 in 108 healthy volunteers.

# About MindMed

MindMed is a clinical stage biopharmaceutical company developing novel products to treat brain health disorders, with a particular focus on psychiatry, addiction, pain and neurology. 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 drug candidates, with and without acute perceptual effects, targeting the serotonin, dopamine and acetylcholine systems.





MindMed trades on the NASDAQ under the symbol MNMD and on the Canadian NEO Exchange 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, including statements regarding the perceived benefits of MM-110 and its potential to address the needs of the opioid crisis and the expectations on timing and outcomes for our Phase 2a trial for MM-

110. Forward-looking information is not based on historical facts, but rather 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-  
T looking statements. 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 year ended December 31, 2021 and its Quarterly Report on Form 10-Q for the period ended March 31, 2022 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  
IT 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.

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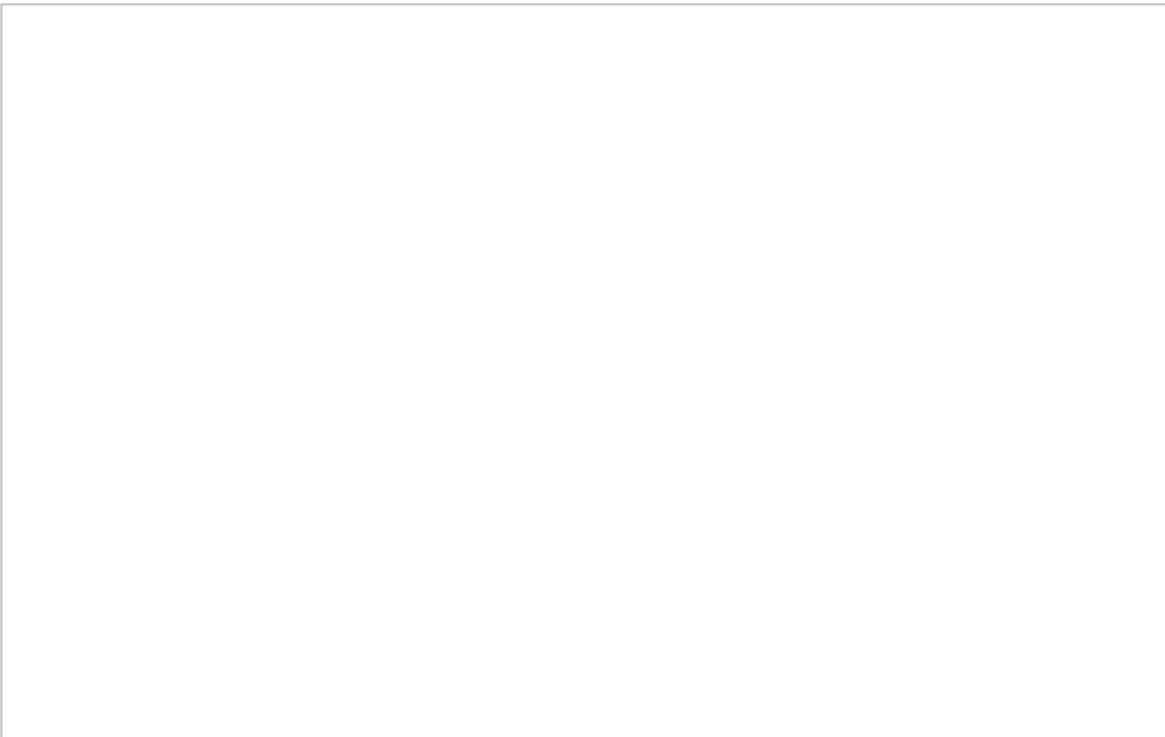


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