

# MindMed Publishes Report by Leading FDA Experts Validating MindMed's MM-120 Drug Development Strategy

Independent Third-Party Firm, Led by Former Senior FDA Officials, Calls Phase 2b Trial "Well-designed" and "Essential"

Report Further Demonstrates that FCM's Proposal to Skip Phase 2 for MM-120 – a Cornerstone of its Plan – is Unrealistic and Would Put MindMed Shareholders' Investments at Risk

Visit www.ProtectMindMed.com for More Information

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 that the Company has published a report by Greenleaf Health, Inc. ("Greenleaf") setting forth an independent expert regulatory assessment of MindMed's MM-120 (lysergide D-tartrate) development strategy. The analysis – led by the former Director and Deputy Director of the Office of New Drugs at the U.S. Food and Drug Administration ("FDA") – focuses on MindMed's clinical and regulatory development strategy for MM-120 and its ongoing Phase 2b trial in patients with generalized anxiety disorder ("GAD"). The findings support MindMed's view that this trial is essential to the development of MM-120 in GAD and answers critical questions to inform a responsible development program. To read the full report, please visit: protectmindmed.com

<u>Greenleaf</u> is a leading FDA regulatory consulting firm run by former senior FDA officials, including Dr. John Jenkins and Dr. Sandy Kweder, former Director and Deputy Director of the Office of New Drugs at the FDA, respectively, the highest office within the Center for Drug Evaluation and Research ("CDER") that oversees new drug approvals at FDA.

In its report, Greenleaf notes the vital importance of the ongoing Phase 2b trial:1

- "After review of the MM-120 regulatory history, relevant regulatory precedent, and applicable regulations and guidance, Greenleaf believes the ongoing Phase 2b doseranging clinical trial is an essential component to the development program for MM-120."
- "To support FDA approval, the MM-120 program will need at least one, and more likely two, positive, adequate and well-controlled trials. The decision by MindMed to first initiate a dose-ranging Phase 2b study is appropriate and sound from a clinical and regulatory perspective."
- "The FDA's feedback on the proposed developed program in no way suggests that it would accept a development program that skips important learnings from a well-

designed and conducted Phase 2b trial in favor of moving directly to a large Phase 3 pivotal program."

Greenleaf also highlights the risks of proceeding without a Phase 2 trial:

- "The ongoing MM-120 Phase 2b trial is designed to address fundamental questions about dose-response, target population, preliminary evidence of efficacy on accepted FDA endpoints for anxiety, and safety that will provide clarity and confidence in designing a Phase 3 program. . . . To initiate Phase 3 trials before these foundational issues have been adequately addressed would substantially increase the chances of a failed trial and/or uninterpretable results."
- "Therefore, the studies from the published literature are not sufficient to support a proposal for streamlining the MM-120 program directly into Phase 3."
- "To enter Phase 3 without a well-articulated target population and indication could result not only in misalignment with the FDA, but more importantly the potential for a Phase 3 program that is difficult to interpret and thus more likely to fail."

In direct contradiction of FCM's proposed ideas for the Company, Greenleaf notes that prior academic studies of LSD should be considered "hypothesis generating" and cannot be solely relied upon for regulatory decision making, stating:

• "As for any novel study drug, the FDA is likely to view the prior published literature around LSD use for the treatment of anxiety as informative and hypothesis generating but not of sufficient detail to allow for an independent review or for regulatory decision making. This is particularly true for LSD given the lack of dose-finding in patients with anxiety and given that the various dosage forms utilized in the published studies do not match what MindMed has developed or intends to use as its to-be-marketed formulation."

FCM MM Holdings, LLC ("FCM"), an entity affiliated with Jake Freeman, Scott Freeman and Chad Boulanger, is waging a distracting and costly campaign to take control of MindMed's Board at the 2023 Annual General Meeting of Shareholders (the "Annual Meeting"), scheduled for June 15, 2023. Based on its publicly released materials, a core tenet of FCM's ideas for the Company is to "skip" Phase 2 for MM-120 in GAD and move directly into Phase 3, in large part by relying on prior academic studies of LSD.

MindMed is already making significant progress on its Phase 2b trial evaluating MM-120 for GAD, as demonstrated by the Company's recent announcement that the trial is over 50% enrolled and dosed. The trial plans to enroll up to 200 participants who will receive a single administration of 25  $\mu$ g, 50  $\mu$ g, 100  $\mu$ g or 200  $\mu$ g of MM-120 or placebo. Topline results are expected to be announced in late 2023.

"As we have consistently said, our regulatory strategy for MM-120 is the right one and was formulated over several interactions with FDA. Our ongoing Phase 2b study answers critical clinical and regulatory questions that will enable us to maximize the speed, efficiency and likelihood of success of our Phase 3 program," said Robert Barrow, Chief Executive Officer and Director of MindMed. "Dr. Jenkins' and Dr. Kweder's extensive experience as senior officials inside FDA, and their objective analysis validating our approach, reinforces that there is no credible basis for FCM's misplaced claim that MindMed could skip its Phase 2 study of MM-120 in GAD and go directly into Phase 3. Further, it underscores that by

supporting this strategy of FCM's, our shareholders would be putting not just the future of MM-120, but also their investments, at significant risk."

# VISIT WWW.PROTECTMINDMED.COM FOR MORE INFORMATION

Due to new U.S. federal rules requiring us to list FCM's nominees in addition to the Board's nominees, your <u>WHITE</u> proxy card this year has more names on it than the six directors to be elected. The inclusion of FCM's nominees on our WHITE proxy card does NOT mean the Board endorses them.

Vote TODAY on the <u>WHITE</u> proxy card FOR all six of the Board's nominees, WITHHOLD on FCM's nominees and FOR the other proposals recommended by your Board.

You can help reject FCM's efforts to take control of the Board by discarding any blue proxy cards and materials you may receive from FCM.

Shareholders will receive proxy materials directly via the preferred method, hard copy or email, specific to each shareholder's account. If you have any questions, or need assistance voting your shares, please contact the firm assisting us in the solicitation of proxies:

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### 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 Canadian NEO Exchange under the symbol MMED.

# **Cautionary Notes and Forward-Looking Statements**

Certain statements in this press 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. Undue reliance should not be placed on forward-looking information, which are inherently uncertain, are based on estimates and assumptions, and are subject to known and unknown risks and uncertainties (both general and specific) that contribute to the possibility that the future events or circumstances contemplated by the forward-looking statements will not occur. There can be no assurance that the plans, intentions or expectations upon which forward-looking statements are based will in fact be realized. Forward-looking information in this press release includes, but is not limited to, statements regarding the potential benefits and development of the Company's product candidates, trials, studies and programs; the strengths and benefits of the Company's strategic plan; the Company's business plans and objectives; the ability of MindMed to achieve success consistent with management's expectations; and the expected impact and results of the Company's corporate governance practices, including of the Company Board's director nominees.

Forward-looking information is based on the opinions and estimates of management of the Company at the date the statements are made, as well as a number of assumptions made by, and information currently available to, the Company concerning, among other things, anticipated performance of its product candidates and programs, business prospects, strategies, regulatory developments, the development of its product candidates into effective products, the ability to produce products if approved, the approval by regulators of any products that are developed, and the non-occurrence of the risks and uncertainties outlined below or other significant events occurring outside of MindMed's normal course of business. Although management of the Company considers these assumptions to be reasonable based on information currently available to it, they may prove to be incorrect.

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 forwardlooking information, including history of negative cash flows; limited operating history; incurrence of future losses; availability of additional capital; changes in market conditions; lack of product revenue; compliance with laws and regulations; changes in government policy; 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 and the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2023 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 Company's profile on SEDAR at www.sedar.com and with the U.S. Securities and Exchange Commission ("SEC") 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 press release as a result of new information, future events, changes in expectations or otherwise.

## Additional Information and Where to Find It

MindMed has filed with the SEC and Canadian securities regulatory authorities on May 1,

2023 a definitive proxy statement on Schedule 14A (the "proxy statement"), containing a form of WHITE universal proxy card, with respect to its solicitation of proxies for the annual general meeting of shareholders of MindMed on June 15, 2023 (the "Annual Meeting"). Details concerning the nominees of MindMed's Board for election at MindMed's Annual Meeting are included in the proxy statement. This press release is not a substitute for the proxy statement or other document that MindMed has filed or may file with the SEC and Canadian securities regulatory authorities in connection with any solicitation by MindMed.

INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO AND THE ACCOMPANYING WHITE UNIVERSAL PROXY CARD) FILED BY MINDMED AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC AND CANADIAN SECURITIES REGULATORS WHEN THEY BECOME AVAILABLE CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MINDMED AND ANY SOLICITATION. Investors and security holders may obtain copies of these documents and other documents filed with the SEC and Canadian securities regulatory authorities by MindMed free of charge through the website maintained by the SEC at <a href="https://www.sec.gov">www.sec.gov</a> or through the Company's profile on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>. Copies of the documents filed by MindMed are also available free of charge by accessing MindMed's website at <a href="https://www.mindmed.co">www.mindmed.co</a>.

# Participants in the Solicitation

This press release is neither a solicitation of a proxy or consent nor a substitute for any proxy statement or other filings that may be made with the SEC and Canadian securities regulatory authorities. Nonetheless, MindMed, its directors and executive officers and other members of management and employees may be deemed under U.S. securities laws and Canadian securities laws to be participants in the solicitation of proxies with respect to a solicitation by MindMed. Information about MindMed's executive officers and directors and other participants in the solicitation, including their respective interests, by security holders or otherwise, is available in the proxy statement. To the extent holdings of MindMed securities reported in the proxy statement for the Annual Meeting have changed, such changes have been or will be reflected on Statements of Change in Ownership on Forms 3, 4 or 5 filed with the SEC and if applicable, on the System for Electronic Disclosure by Insiders (SEDI) in accordance with insider reporting requirements of Canadian securities laws. These documents are or will be available free of charge at the SEC's website at <a href="https://www.seci.com">www.seci.com</a> or updated filings on SEDI at <a href="https://www.sedi.ca">www.sedi.ca</a>.

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Source: Mind Medicine (MindMed) Inc.