December 5, 2024

MindMed Awarded Innovation Passport Designation by the United Kingdom (UK) Innovative Licensing and Access Pathway (ILAP) Steering Group for MM120 Orally Disintegrating Tablet (ODT) for Generalized Anxiety Disorder (GAD)

- Innovation Passport Designation Aims to Accelerate Time to Market and Facilitate Patient Access to Innovative Medicines -

NEW YORK--(BUSINESS WIRE)-- Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (the "Company" or "MindMed"), a clinical-stage biopharmaceutical company developing novel product candidates to treat brain health disorders, today announced that MM120 ODT, a pharmaceutically optimized form of lysergide D-tartrate (LSD), has been granted an Innovation Passport for the potential treatment of GAD under ILAP by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA). The Innovation Passport is the entry point to the ILAP, which aims to accelerate time to market and facilitate patient access to medicines in the U.K.

“Receiving the Innovation Passport designation is recognition of MM120 ODT’s potential to address GAD, one of the most critical and underserved needs in mental health,” said Rob Barrow, Chief Executive Officer of MindMed. “Following the receipt of Breakthrough Therapy Designation by the U.S. Food and Drug Administration, the Innovation Passport designation underscores our commitment to bringing MM120 ODT to people living with GAD and our dedication to working closely with the MHRA to expedite patient access. We are determined to offer new hope and transformative solutions where current treatments have failed to meet the needs of those who suffer from this serious condition.”

Recipients of the Innovation Passport are granted access to a range of development tools to support the design, development, and approvals process in the U.K., as well as opportunities for enhanced regulatory and other stakeholder input. Specific benefits of ILAP include the potential for a 150-day accelerated Marketing Authorization Application assessment, rolling review and a continuous benefit risk assessment. The ILAP is delivered in partnership by the MHRA, the All Wales Therapeutics and Toxicology Centre, the National Institute for Health and Care Excellence and the Scottish Medicines Consortium, part of Healthcare Improvement Scotland.

About Generalized Anxiety Disorder (GAD)

Anxiety disorders are the world’s most common mental disorders, affecting 301 million people in 2019.[1] In the U.K., more than eight million people live with an anxiety disorder.[2]

GAD is chronic and debilitating and results in fear, continuing anxiety, and a constant feeling of being overwhelmed. It is characterized by excessive, persistent, and unrealistic worry about everyday things. GAD is underdiagnosed and underserved and is associated with 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 two decades.

About MM120 ODT

MM120 ODT (lysergide D-tartrate or LSD) is a synthetic ergotamine belonging to the group of classic, or serotonergic, psychedelics which acts as a partial agonist at human serotonin-2A (5-HT2A) receptors. MM120 ODT is MindMed's proprietary and pharmaceutically optimized form of LSD. MM120 ODT is an advanced formulation incorporating Catalent's Zydis® ODT fast-dissolve technology which has a unique clinical profile with more rapid absorption, improved bioavailability and reduced gastrointestinal side effects.

The MM120 ODT Phase 3 clinical development program includes the Voyage and Panorama studies in generalized anxiety disorder (GAD) and the Emerge study in major depressive disorder (MDD). Additional clinical indications are under consideration. MindMed's Phase 2b study, MMED008, met its primary and key secondary endpoints and demonstrated rapid, clinically meaningful, and statistically significant improvements on the Hamilton Anxiety Rating Scale (HAM-A) at Week 4 and Week 12, with a 65% clinical response rate and 48% clinical remission rate sustained to Week 12 in the MM120 100 µg cohort. MM120 was generally well-tolerated in this study, with most adverse events rated as mild to moderate, transient, and occurring on the dosing day and being consistent with the expected acute effects of the trial drug.

Based on the significant unmet medical need in the treatment of GAD along with the initial clinical data from the Phase 2b study and other research conducted by MindMed, the U.S. Food & Drug Administration granted Breakthrough Therapy Designation for the MM120 program in GAD.

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. MindMed trades on NASDAQ under the symbol MNMD.

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 the potential benefits of Innovative Licensing and Access Pathway; Company's beliefs regarding potential benefits of its product candidates; anticipated upcoming milestones, trials and studies; and potential additional indications for MM120 ODT. 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; 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," 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.sedarplus.ca 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.

References

1. Yang, X., Fang, Y., Chen, H., Zhang, T., Yin, X., Man, J., Yang, L., & Lu, M. (2021). Global, regional and national burden of anxiety disorders from 1990 to 2019: Results from the Global Burden of Disease Study 2019. *Epidemiology and Psychiatric Sciences, 30,* Article e36. https://doi.org/10.1017/S2045796021000275

2. Mental Health UK, What is anxiety disorder? - Mental Health UK, accessed November 29, 2024

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