Optimi Health & ATMA Receive No Objection Letter from Health Canada for Phase 2 Clinical Trial

Trial to study Major Depressive Disorder using Optimi's GMP natural psilocybin capsules in conjunction with therapy

VANCOUVER, BC – August 28, 2024 – Optimi Health Corp. (CSE: OPTI) (OTCQX: OPTHF) (FRA: 8BN) ("**Optimi**" or the "**Company**"), a GMP-compliant, Health Canada-licensed manufacturer of psychedelics pharmaceuticals specializing in botanical psilocybin and MDMA, is pleased to announce the receipt of a No Objection Letter (NOL) from Health Canada. This authorization permits the use of the Company's GMP natural psilocybin extract capsules in a Phase 2 clinical trial, conducted in collaboration with ATMA Journey Centers LTD. ("**ATMA**").

Advancing Clinical Validation in Canada

The approval to initiate this Phase 2 clinical trial represents a pivotal moment in the clinical development of Optimi's GMP natural psilocybin extract capsules. Building on its established status as a treatment option for patients with treatment-resistant depression (TRD) in Australia, this trial will provide a rigorous evaluation of the capsules in 200 participants within a controlled clinical environment in Canada. The study is scheduled to commence in the coming months, and is expected to yield valuable insights that will contribute to the broader understanding of psilocybin as a potential therapeutic option within the Canadian healthcare system.

Pathway to Further Clinical Development

This Phase 2 trial, focused within Canada, is designed to assess the safety, efficacy, and therapeutic potential of Optimi's psilocybin extract capsules. The results of this study will be crucial in advancing the clinical understanding of natural psilocybin's role in treating mental health conditions, with the ultimate goal of integrating this therapy into clinical practice through official registration of the drug in Canada.

"We are deeply grateful to Health Canada for approving our GMP psilocybin extract for this pivotal Phase 2 trial," said Bill Ciprick, CEO of Optimi. "This approval not only propels our clinical validation efforts in Canada but also underscores our unique position in the global psychedelics industry. We are thrilled to be partnering with ATMA on this groundbreaking study, which complements our ongoing collection of Real World Evidence (RWE) from patients in Australia."

Ciprick added that Optimi is now among the very few companies worldwide that can both clinically validate a drug in a controlled setting and gather real-world data across diverse patient populations. "As a GMP-compliant, end-to-end manufacturer, we are uniquely positioned to access and leverage this comprehensive data set, ensuring our products meet the highest standards of quality and efficacy on a global scale."

Unique Focus on Frontline Mental Healthcare Workers

A distinguishing feature of this trial is its focus on improving the mental health of frontline mental healthcare workers. The Phase II study, titled *A Phase II Study Assessing the Efficacy of Psilocybin-assisted Psychotherapy when Administered to Frontline Mental Healthcare Workers Suffering from Major Depressive Disorder related to COVID-19*, will evaluate the effectiveness of psilocybin in treating COVID-19-related Major Depressive Disorder (MDD) in 200 frontline

healthcare workers. The trial will also explore the potential of psilocybin to enhance the professional capacities of these workers, particularly in the context of psychedelic therapy.

Background and Importance of the Study

Psychological illness imposes a significant global burden, with one in five adults experiencing mental health disorders annually, and nearly a third facing such issues in their lifetime.[1] Major Depressive Disorder (MDD) is particularly prevalent and is expected to become the leading cause of disease burden by 2030.[2] The COVID-19 pandemic has exacerbated these challenges, especially for frontline healthcare workers who have endured increased stress, hazardous conditions, and stigmatization. These factors have led to heightened mental health concerns, often resulting in long-term consequences like burnout, anxiety, and depression.[3]

Frontline healthcare workers, already disproportionately affected by mental health issues compared to the general population, have seen these challenges worsen due to the severe circumstances of the pandemic. Occupational burnout, characterized by emotional exhaustion, detachment, and decreased job satisfaction, contributes to serious outcomes such as PTSD, increased suicide rates, and reduced quality of care. Traditional pharmacotherapies for mental health disorders often come with limitations, including variable efficacy and undesirable side effects, highlighting the need for novel treatments with better safety profiles and more rapid, sustained effects.[4]

Psilocybin, a compound derived from certain mushrooms, has shown promise as a potential breakthrough treatment for conditions like MDD, treatment-resistant depression, and anxiety. Recent studies have demonstrated its efficacy and safety, leading to growing interest in its therapeutic potential. This trial will investigate psilocybin's effectiveness in treating COVID-19-related MDD in frontline mental healthcare workers, while also exploring its impact on enhancing their professional capacities, particularly in the realm of psychedelic therapy. This research could provide crucial insights into new treatment options for those most affected by the pandemic's mental health challenges.

About Optimi Health Corp.

Optimi Health Corp. (CSE: OPTI) (OTCQX: OPTHF) (FRA: 8BN) is a leading psychedelics pharmaceutical manufacturer licensed by Health Canada. Specializing in controlled substances such as botanical psilocybin and MDMA, Optimi is dedicated to supplying safe, top-tier GMP-grade products and APIs to researchers, drug developers, and authorized patients worldwide. Optimi's facilities in Princeton, British Columbia, are purpose-built to develop proprietary formulations under strict GACP and GMP conditions, ensuring unparalleled quality and reliability. The Company is committed to being the most trusted supplier of safe psychedelic drug candidates globally.

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[1] National Institute of Mental Health

[2] Nature

[3] National Library of Medicine

[4] Ibid

Forward-Looking Statements

This news release contains forward-looking statements and forward-looking information within the meaning of Canadian securities legislation (collectively, "forward-looking statements") that relate to Optimi's current expectations and views of future events. Any statements that express, or involve discussions as to, expectations, beliefs, plans, objectives, assumptions, or future events or performance (often, but not always, through the use of words or phrases such as "will likely result," "are expected to," "expects," "will continue," "is anticipated," "anticipates," "believes," "estimated," "intends," "plans," "forecast," "projection," "strategy," "objective," and "outlook") are not historical facts and may be forward-looking statements. These statements may involve estimates, assumptions, and uncertainties that could cause actual results or outcomes to differ materially from those expressed in such forward-looking statements. No assurance can be given that these expectations will prove to be correct, and such forward-looking statements included in this news release should not be unduly relied upon. These statements speak only as of the date of this news release.

Forward-looking statements are based on a number of assumptions and are subject to a number of risks and uncertainties, many of which are beyond Optimi's control, which could cause actual results and events to differ materially from those that are disclosed in or implied by such forward-looking statements. Optimi undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as may be required by law. New factors emerge from time to time, and it is not possible for Optimi to predict all of them or assess the impact of each factor or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement. Any forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement.

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