

Optimi Health Submits Phase I Clinical Trial Application Combining The Use Of Proprietary Psilocybin and MDMA Drug Candidates In Healthy Therapists

First-of-its-kind clinical trial establishes the Company's drug pipeline and strategic plan to supply thousands of therapists

For immediate release:

February 7, 2023

Vancouver, British Columbia – [Optimi Health Corp. \(CSE: OPTI\)](#) (OTCQX: OPTHF) (FRA: 8BN) (“Optimi” or the “Company”), an end-to-end Canadian-based drug manufacturer and formulator licensed by Health Canada to produce and supply natural, GMP-grade psilocybin, synthetic psychedelic substances, and high-quality functional mushrooms, is pleased to announce the submission of its clinical trial application (CTA) for a Phase I combinatorial study that will document the safety of Optimi’s natural psilocybin standardized extract and proprietary 3,4-methylenedioxy-methamphetamine (MDMA) drug candidate in healthy therapist subjects.

Yesterday, Optimi announced the successful completion of its novel MDMA drug candidate, OPTI-MHCL, which was tested for purity on-site with a result of >99% over multiple consistent batches by Chief Science Officer, Justin Kirkland.

Both drug candidates are scheduled to be administered in the clinical trial and will be manufactured in-house at Optimi’s 20,000 square foot facilities in Princeton, British Columbia.

The investigator-initiated double-blind placebo-controlled study is being conducted through [ATMA Journey Centers](#) in Calgary, Alberta, and will be the first-of-its-kind to directly compare the acute effects of these substances within the same clinical study. ATMA is currently the only Canadian organization that has completed a successful Phase I safety trial with natural psilocybin in healthy therapists.

The primary objective of the trial is to demonstrate the safety and tolerability of the combinatory use of natural psilocybin and MDMA in healthy participants, broadly validating Optimi’s offering and, in later stages, indicating the suitability for use of these substances, combined and separately, in experiential training by psychedelic therapy practitioners.

Optimi CEO, Bill Ciprick, says the Company’s operational investments and full-scale commercialization in 2022 have set it up to make an immediate impact in 2023.

“With an estimated 25,000 to 100,000 therapists needed to support the millions of people suffering with post-traumatic stress disorders, Optimi feels strongly that clinical research undertaken at this stage by GMP cultivators and formulators in partnership with mental health training services such as ATMA should be geared toward meeting this immediate need,” said Ciprick. “Therapists provided experiential training with both substances will in turn be able to provide greater value and higher standards of care to patients undergoing these treatments.”

The single site, double-blind, five arm study will include 25 participants randomized into one of five groups to undergo a supervised experimental session. Participants will receive either 25mg of natural psilocybin and a placebo, 125mg of MDMA and a placebo, or 25mg of natural psilocybin in combination with MDMA (50mg, 80mg, or 125mg).

The Company will collect data, including blood pressure, temperature, heart rate, ECG readings, and will assess both safety and additional markers, such as the mystical experience questionnaire in the healthy therapist subjects that have consumed Optimi's proprietary MDMA formulation and natural GMP psilocybin. Further, the Company is exploring the potential inclusion of novel, non-invasive, whole-body electrophysiological technology that would provide real-time functional analyses of 24 organs and glands on each participant.

Optimi has set the important goal of using its operational strength and end-to-end capabilities to tackle the global mental health crisis in 2023 and beyond.

"This is about helping people heal. Optimi Health receives emails from patients and physicians on an almost daily basis, searching for our help in obtaining some level of mental health support and asking when these modalities might be available to them," said Ciprick. "They are entrusting us to deliver because they still have hope, and that is why we have set an ambitious course of action in 2023 that will help therapists complete their training in time to bring them the support they need. This trial offers a tangible step forward in that essential process, for which the endpoint is providing relief for countless sufferers."

Optimi Health products are still being investigated through a clinically validated development program for the purpose of applying for market authorization. Though the Company has conducted rigorous internal analysis, the safety and efficacy of our products are still being formally established.

FOR INTERVIEW REQUESTS OR FURTHER INFORMATION PLEASE CONTACT:

Michael Kydd
Investor Relations
Email: investors@optimihealth.ca
Phone: +1 (902) 880 6121
Web: www.optimihealth.ca

ABOUT OPTIMI (CSE: OPTI) (OTCQX: OPTHF) (FRA: 8BN)

Optimi Health Corp. is an end-to-end Canadian-based drug manufacturer and formulator licensed by Health Canada to produce and supply natural, GMP-grade psilocybin and synthetic psychedelic substances, as well as functional mushrooms that focus on the health and wellness markets. Built with the purpose of manufacturing pre-clinical to commercial scale Active Pharmaceutical Ingredients and finished product, our two GMP facilities in Princeton, British Columbia have fully integrated quality management systems in place, which include regular facility audits and external qualifications of all raw material and component suppliers to ensure the highest level of compliance. The Company's goal is to be the number one trusted, compassionate supplier of safe drug products throughout the world.

ABOUT ATMA JOURNEY CENTERS

ATMA is pioneering a therapist-centred and therapist-driven business model for the psychedelic industry. Education, training, clinical trials, and business support services in the largest online community platform for psychedelic practitioners are all being developed to assist mental healthcare professionals in adopting psychedelic-assisted therapy. ATMA provides a clear,

guided path for healthcare professionals and clinics to build psychedelic-assisted therapies into their current practices.

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 and may involve estimates, assumptions and uncertainties which 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. In particular and without limitation, this news release contains forward-looking statements pertaining to activities proposed to be conducted under the Company’s approved Health Canada dealer’s licence and associated business related to Psilocybin, Psilocin, other psychedelic substances, some being synthetically formulated, and Optimi’s plans, focus and objectives.

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. Such risks and uncertainties include, but are not limited to, the impact and progression of the COVID-19 pandemic and other factors set forth under “Forward-Looking Statements” and “Risk Factors” in the Company’s Annual information Form dated January 9, 2023, and other continuous disclosure filings available under Optimi’s profile at www.sedar.com. 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 such 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.