Optimi Health Provides Dealer License Update and Comments on Health Canada's Amendments to the Special Access Program (SAP)

SAP amendment allows practitioners to request access to psychedelic drugs for patients with serious or lifethreatening conditions on a case-by-case basis

VANCOUVER, British Columbia, Jan. 05, 2022 (GLOBE NEWSWIRE) -- **Optimi Health Corp.** (CSE: OPTI) (OTCQB: OPTHF) (FRA: 8BN) ("Optimi" or the "Company"), developers of a vertically integrated mushroom brand targeting functional and novel psychedelic compounds for the health and wellness sector, is pleased to report the successful completion of the Health Canada inspection on December 21, 2021. The Company is in close contact with the regulator and welcomes finalization of the process in the coming weeks. Additionally, Optimi commends Health Canada for taking an active leadership role in finding solutions for the ongoing Canadian mental health crisis including access to psilocybin for therapeutic purposes through the Special Access Program (SAP).

Background

In Canada, drugs are authorized for sale only once they have successfully gone through the drug review process, including evaluation of safety, effectiveness and quality. However, Health Canada's SAP allows practitioners to request access to drugs that are not available in Canada for the emergency treatment of patients with serious or life-threatening conditions who have exhausted other treatment options. Due to regulatory changes made in 2013, restricted drugs have not been made available through the SAP.

Since then, clinical trials have been the only avenue by which the sale of a restricted drug could be authorized for patient treatment. While clinical trials remain the best mechanism to authorize the sale of drugs, there are barriers to patient participation including geography or lack of clinical trial recruitment.

Yet, there has been ongoing scientific research into the efficacy and safety of certain restricted drugs. In response, Health Canada has today announced a reversal of the regulatory changes made in 2013 to Part C of the Food and Drug Regulations and has restored potential access to restricted drugs through the SAP.

What the regulatory amendments mean for Canadians

The regulatory amendments will allow physicians to request patient access to psychoactive substances, like psilocybin and MDMA, for psychedelic-assisted therapy. Decisions will remain on a case-by-case basis and will be reserved for serious, treatment-resistant or life-threatening conditions. The amendments have the potential to positively affect the lives of people experiencing serious mental health conditions and end-of-life distress when other therapies have failed, are unsuitable or are unavailable in Canada.

"Optimi acknowledges the Trudeau government, former Health Minister Patty Hajdu, current Health Minister, Jean-Yves Duclos, Minister of Mental Health and Addictions, Carolyn Bennett, and officials within Health Canada's Legislative and Regulatory Affairs Department for giving the public an opportunity to consult on this important program," notes Bill Ciprick, Optimi's CEO. "We believe the amendments will bring much-needed relief and comfort to the hundreds of veterans, first-responders and Canadians who will immediately benefit from psychedelic psychotherapy to help with treatment-resistant depression that is considered serious and life-threatening by their physician."

Our vision

Upon approval of the Dealer's license, Optimi's vision is to be the leader in providing safe supply and the highest-grade GMP certified psilocybin across Canada and the world. We agree with Health Canada there should be continued research to test the efficacy and safety of psychedelic drugs. Our first clinical trial to determine the safe and effective standardized micro-dose of psilocybin for mental health including anxiety and depression is currently awaiting Health Canada approval. Earlier last year, Optimi received a Section 56 exemption for research purposes and this initial trial will be conducted at the Bloom Clinic, which is Calgary's first psychedelic assisted therapy centre.

"Optimi is committed to the safety and efficacy of our product, and we look forward to supplying Canadian and global institutions with the highest-quality psilocybin in the market," said Mr. Ciprick.

The Company also announces it has issued 50,000 common shares, at a deemed price of \$0.465 per share, subject to a hold period expiring May 5, 2022, in consideration of services provided.

On Behalf of the Board of Directors,

Bill Ciprick Chief Executive Officer Optimi Health Corp.

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

Optimi is developing a sophisticated mushroom brand that focuses on the health and wellness markets. With a vertically integrated approach, Optimi intends to cultivate, extract, process and distribute high quality functional mushroom products at its two facilities comprising a total of 20,000 square feet nearing completion in Princeton, British Columbia. To fully investigate the science of mushrooms, the Company has received a research exemption under Health Canada Food and Drug Regulations (FDR) for the use of Psilocybin and Psilocin for scientific purposes via its wholly owned subsidiary Optimi Labs Inc. Optimi has also applied for a dealer's license under Canada's Narcotic Control Regulations governing possession, distribution, sale, laboratory analysis of and research and development of Psilocybin and Psilocin formulations. Optimi is committed to expert cultivation and quality production subject to and in accordance with the terms of all applicable laws and governing regulations to ensure safe, superior Canadian fungi production. Find out more at: https://optimihealth.ca/.

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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 the Company's potential Nasdaq listing, the dealer's license application, activities proposed to be conducted under the Company's research exemption and associated business related to Psilocybin and Psilocin 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 Final Prospectus dated February 12, 2021. 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.

The CSE does not accept responsibility for the adequacy or accuracy of this release.