

## Core One Labs Applauds FDA's Draft Guidance on Clinical Trials for Psychedelic Drugs

Vancouver, British Columbia, Canada – June 26, 2023 – **Core One Labs Inc.** (CSE: **COOL**), (OTCQB: **CLABF**), (Frankfurt: **LD6**, WKN: A3CSSU) (the “Company” or “Core One”), commends the U.S. Food and Drug Administration (FDA) for publishing a groundbreaking new draft guidance on clinical trials for psychedelic drugs.

The FDA’s draft guidance underscores the crucial considerations that researchers must address when exploring the potential therapeutic applications of psychedelic drugs in treating various medical conditions, including psychiatric and substance use disorders. Importantly, this is the first FDA draft guidance providing instructions to the industry for designing clinical trials for psychedelic drugs.

In recent years, there has been a growing interest in the potential therapeutic benefits of psychedelic drugs. These compounds are being investigated for their ability to treat conditions such as depression, post-traumatic stress disorder (PTSD), substance use disorders, and others. However, designing clinical studies to evaluate the safety and efficacy of these compounds presents unique challenges that demand careful attention.

Dr. Tiffany Farchione, the Director of the Division of Psychiatry in the FDA's Center for Drug Evaluation and Research, stated, "Psychedelic drugs show initial promise as potential treatments for mood, anxiety, and substance use disorders. However, these are still investigational products." Dr. Farchione further added, "By publishing this draft guidance, the FDA hopes to outline the challenges inherent in designing psychedelic drug development programs and provide information on how to address these challenges. The goal is to help researchers design studies that will yield interpretable results capable of supporting future drug applications."

The draft guidance aims to provide valuable advice to researchers on study design and other critical considerations as they develop medications containing psychedelics. It specifically focuses on "classic psychedelics," such as psilocybin and lysergic acid diethylamide (LSD), which act on the brain's serotonin system, as well as "entactogens" or "empathogens" like methylenedioxymethamphetamine (MDMA).

Throughout the document, the FDA outlines fundamental considerations for the drug development process, including trial conduct, data collection, subject safety, and new drug application requirements. Notably, psychedelic drugs can produce psychoactive effects, including mood and cognitive changes and hallucinations. Consequently, preventing misuse and ensuring drug safety necessitate meticulous planning and the implementation of appropriate safety measures during clinical development. For psychedelics currently categorized as Schedule I controlled substances, the draft guidance emphasizes compliance with relevant Drug Enforcement Administration regulatory requirements during activities associated with investigations under an Investigational New Drug Application.

The evidentiary standard for establishing the effectiveness of psychedelic drugs is the same as that for all other drugs. However, investigators need to consider unique factors when designing

their clinical trials to ensure they meet the criteria for being deemed adequate and well-controlled. The draft guidance also addresses the role of psychotherapy in psychedelic drug development, safety monitoring considerations, and the importance of characterizing dose-response and the durability of any treatment effect.

To foster an inclusive approach, the FDA encourages public participation and invites comments on the draft guidance. Interested parties are encouraged to submit their comments within 60 days to ensure consideration by the agency.

Core One Labs fully supports the FDA's efforts to provide comprehensive guidance on the development of clinical trials for psychedelic drugs. As a company at the forefront of psychedelic medicine research, Core One Labs remains committed to advancing the understanding and utilization of these compounds for the benefit of patients suffering from various medical conditions.

The Company is also pleased to announce that its wholly-owned subsidiary, GMP Drug Inc. (“**GMP**”), has successfully achieved its milestone (the “**Milestone**”), through the completion of the first synthetic production of psilocin at the GMP manufacturing facility. Achievement of this Milestone lays the groundwork for the Company’s large-scale production of psychedelic compounds at a GMP certified facility. Following achievement of the Milestone, it is anticipated that the Company will issue 1,029,412 common shares at a deemed price of \$0.68 per common share (the “**Bonus Shares**”) on or about July 5, 2023 to the former shareholders of GMP to satisfy bonus obligations originally agreed to at the time of the acquisition of GMP.

### **About Core One Labs Inc.**

Core One Labs is a life sciences biotechnology research and development company focused on bringing psychedelic medicines to market through the development and production of psychedelic compounds, the advancement of psychedelic assisted treatments, and the integration of novel delivery systems technology.

The Company has a multi-faceted business approach and incorporates several complementary lines of businesses and units in establishing itself as an industry leader in the rapidly growing and emerging psychedelics market space.

Core One, through its wholly owned subsidiary Vocan Biotechnologies Inc., has developed and filed for patent protection of a proprietary psilocybin production system using engineered bacteria. It is also the holder of 4 provisional patents for the development of psychedelic-based pharmaceutical formulations targeting neurological and mental health disorders, under its 100% owned subsidiary Akome Biotech Ltd., and 3 provisional patents under its other 100% owned subsidiary, Awakened Biosciences Inc., for additional synthetic technologies for psilocybin and psilocin production methods.

In addition to the development of psychedelics and psychedelic compounds, Core One holds an interest in four medical clinics which maintain a combined database of more than 275,000 patients. Through its clinics the Company intends to integrate a roll out of its intellectual property related to psychedelic technologies and participate in the advancement of psychedelic-based treatments for mental health disorders.

Core One Labs Inc.

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In addition, psilocybin is currently a Schedule III drug under the *Controlled Drugs and Substances Act* (Canada) and it is a criminal offence to possess substances under the *Controlled Drugs and Substances Act* (Canada) without a prescription or authorization. Health Canada has not approved psilocybin as a drug for any indication. Core One does not have any direct or indirect involvement with illegal selling, production, or distribution of psychedelic substances in jurisdictions in which it operates. While Core One believes psychedelic substances can be used to treat certain medical conditions, it does not advocate for the legalization of psychedelics substances for recreational use. Core One does not deal with psychedelic substances, except within laboratory and clinical trial settings conducted within approved regulatory frameworks.