Cybin and Clinilabs Granted Schedule I DEA License for CYB003 Phase 1/2a First-In-Human Clinical Trial

August 17, 2022

TORONTO--(BUSINESS WIRE)-- Cybin Inc. (NEO:CYBN) (NYSE American:CYBN) ("**Cybin**" or the " **Company**"), a biopharmaceutical company focused on progressing "Psychedelics to Therapeutics™", and its partner Clinilabs Drug Development Corporation ("Clinilabs"), a global, full-service contract research organization with deep expertise in central nervous system drug development, today announced that the U.S. Drug Enforcement Agency ("DEA") has granted a Schedule I license to support the first-in-human Phase 1/2a clinical trial of CYB003, a proprietary deuterated psilocybin analog that is being developed for the treatment of major depressive disorder ("MDD").

"Obtaining a DEA license for our Phase 1/2a trial is the final step clearing the way to begin dosing participants in our first-in-human study of CYB003. Our rigorous recruitment and enrollment process is well under way, and we are excited to commence dosing of our first cohort of participants," said Doug Drysdale, Chief Executive Officer of Cybin.

The DEA license is a federal requirement for any investigators who intend to study, produce, analyze, or otherwise work with Schedule I controlled substances.

About the CYB003 Phase 1/2a Trial
The Phase 1/2a trial is a randomized, double-blind, placebo-controlled study evaluating people with moderate to severe MDD. Participants will receive two administrations (placebo/active and active/active) and a response/remission will be assessed at Week 3 (after first dose) and at Week 6 (after second dose). Importantly, participants in the trial that are currently being treated with antidepressants will be allowed to remain on their antidepressant medication.

Using the Montgomery-Asberg Depression Rating Scale, the trial will assess rapid onset of antidepressant effect on the day of dosing. The study will also evaluate the incremental benefit of a second dose of CYB003 when administered at Week 3 and will provide important PK and safety data to determine a clinical path forward. An optional period of assessment will help determine the durability of treatment effect out to 12 weeks. The detailed Phase 1/2a study protocol is available at clinicaltrials.gov under the Identifier number: NCT05385783.

This research study is recruiting individuals between the ages of 21 and 55 who have been diagnosed with MDD and who are currently taking an antidepressant medication that is not working to their satisfaction. Participation includes 11 outpatient visits and two 2-day inpatient stays. Participants who are located within reasonable travel distance to the Clinilabs Eatontown, New Jersey clinical research unit, may pre-screen for study entry at www.depressionpsychedelicstudy.com or by telephone at (212) 994-4567.

About CYB003
CYB003 is a deuterated analog of psilocybin, which is part of a family of molecules called indolamines that include more common neurotransmitters, such as serotonin. Psilocybin is dephosphorylated to form its metabolite psilocin, which can cross the blood-brain-barrier. Given its structural similarity to serotonin, psilocin can easily activate the serotonin 5-HT2A receptor.

CYB003 is designed to potentially address the challenges and limitations of oral psilocybin. Based on preclinical data, CYB003 achieved less variability in plasma levels, faster onset of action, and shorter duration of effect. We believe CYB003 has the potential to reduce time and resource burden on patients, providers, and payers, and possibly improve scalability and accessibility of treatment.

About Cybin
Cybin is a leading ethical biopharmaceutical company, working with a network of world-class partners and internationally recognized scientists, on a mission to create safe and effective therapeutics for patients to address a multitude of mental health issues. Headquartered in Canada and founded in 2019, Cybin is operational in Canada, the United States, the United Kingdom, the Netherlands and Ireland. The Company is focused on progressing Psychedelics to Therapeutics by engineering proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health disorders.

About Clinilabs Drug Development Corporation
Clinilabs Drug Development Corporation is the only global, full-service contract research organization focused exclusively on central nervous system ("CNS") drug development. With deep expertise in CNS, we are committed to the development of medicines that treat a range of psychiatric, neurological and substance use disorders, as well as rare and ultra-rare CNS diseases. Clinilabs partners with pharmaceutical and biotechnology companies to deliver a complete, first-in-human to Phase 3

spectrum of high quality, timely, and cost-effective clinical drug development services, with the shared goal of speeding new CNS medicines to market. We are process-driven yet structured to be nimble, providing personalized service that meets the needs of customers and projects of all sizes. Clinilabs has conducted more than 675 CNS clinical trials in our 22-year history and played a pivotal role in the approval of 19 new therapies across 10 CNS indications to help transform the lives of patients worldwide.

Cautionary Notes and Forward-Looking Statements
Certain statements in this press release constitute forward-looking information. All statements other than statements of historical fact contained in this press release, including, without limitation, statements regarding Cybin's future, strategy, plans, objectives, goals and targets, and any statements preceded by, followed by or that include the words "believe," "expect," "aim," "intend," "plan," "continue," "will," "may," "would," "anticipate," "estimate," "forecast," "predict," "project," "seek," "should" or similar expressions or the negative thereof, are forward-looking statements. Forward-looking statements in this news release include statements related to the results of the Company's CYB003 preclinical studies, statements regarding the Company's CYB003 Phase 1/2a trial and anticipated results, the Company's recruitment of patients for its CYB003 Phase 1/2a trial, and the Company's plan to engineer proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health conditions.

These forward-looking statements are based on reasonable assumptions and estimates of management of the Company at the time such statements were made. Actual future results may differ materially as forward-looking statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results, performance, or achievements of the Company to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors, among other things, include: implications of the COVID-19 pandemic on the Company's operations; fluctuations in general macroeconomic conditions; fluctuations in securities markets; expectations regarding the size of the psychedelics market; the ability of the Company to successfully achieve its business objectives; plans for growth; political, social and environmental uncertainties; employee relations; the presence of laws and regulations that may impose restrictions in the markets where the Company operates; and the risk factors set out in the Company's management's discussion and analysis for the period ended June 30, 2022 and the Company's listing statement dated November 9, 2020, which are available under the Company's profile on www.sedar.com and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov. Although the forward-looking statements contained in this news release are based upon what management of the Company believes, or believed at the time, to be reasonable assumptions, the Company cannot assure shareholders that actual results will be consistent with such forward-looking statements, as there may be other factors that cause results not to be as anticipated, estimated or intended. Readers should not place undue reliance on the forward-looking statements and information contained in this news release. The Company assumes no obligation to update the forward-looking statements of beliefs, opinions, projections, or other factors, should they change, except as required by law.

Cybin makes no medical, treatment or health benefit claims about Cybin's proposed products. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated claims regarding psilocybin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of psilocybin, psychedelic tryptamine, tryptamine derivatives or other psychedelic compounds can diagnose, treat, cure or prevent any disease or condition. Rigorous scientific research and clinical trials are needed. Cybin has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products do not imply that Cybin verified such in clinical trials or that Cybin will complete such trials. If Cybin cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on Cybin's performance and operations.

Neither the Neo Exchange Inc. nor the NYSE American LLC stock exchange have approved or disapproved the contents of this news release and are not responsible for the adequacy and accuracy of the contents herein.

Investor & Media:
Jeanine M. Falinski, MBA
Vice President, Strategy & Corporate Development
Clinilabs Drug Development Corporation
jfalinski@clinilabs.com

Leah Gibson
Vice President, Investor Relations & Strategic Communications
Cybin Inc.
irteam@cybin.com – or – media@cybin.com

Gabriel Fahel
Chief Legal Officer
Cybin Inc.
1-866-292-4601

Source: Cybin Inc.