



Cybin Partners with Clinilabs Drug Development Corporation for Phase 1/2a Trial Evaluating CYB003 for the Treatment of Major Depressive Disorder

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TORONTO--(BUSINESS WIRE)-- [Cybin Inc. \(NEO:CYBN\)](#) (NYSE American:CYBN) (**Cybin** or the **Company**), a biopharmaceutical company focused on progressing “Psychedelics to Therapeutics™”, today announced that it has partnered with [Clinilabs Drug Development Corporation](#) (“Clinilabs”), a global, full-service contract research organization with deep expertise in central nervous system drug development, to carry out the Company’s Phase 1/2a clinical trial of CYB003, a proprietary deuterated psilocybin analog. [CYB003](#) will be the first psilocybin analog to be evaluated in Phase 1/2a development for the treatment of major depressive disorder (“MDD”).

“We are delighted to partner with the Clinilabs team as we progress this important program toward a first-in-human Phase 1/2a trial. Clinilabs brings a unique combination of scientific and operational experience and deep expertise in clinical research across a range of psychiatric, neurological and substance use disorders,” said Doug Drysdale, Chief Executive Officer of Cybin. “Clinilabs is ideally suited to help us accelerate the regulatory pathway for this promising treatment candidate and ultimately, to effectively treat those suffering with MDD.”

In multi-species preclinical studies, CYB003 demonstrated significant advantages over classic psilocybin including, less variability in plasma levels, faster onset of action, shorter duration of effect and potentially better tolerability for an overall better outcome for patients. Cybin recently announced the completion of its IND-enabling *in vivo* preclinical studies of CYB003. Data from these studies support the advancement toward an investigational new drug (“IND”) filing with the U.S. Food and Drug Administration (“FDA”) for the Phase 1/2a clinical trial. Cybin intends to submit an IND to the FDA in the second quarter of 2022 and expects to initiate the Phase 1/2a trial in mid-2022.

“Approximately one-third to one-half of people with MDD demonstrate an inadequate response to antidepressant drug treatment. Treatment options for these patients currently are limited to dose escalation, switching or combining antidepressants, or augmentation therapy, often with unsatisfactory results,” said Dr. Gary Zammit, President & CEO of Clinilabs. “It is a privilege to be working with Cybin, an innovator in the development of novel psychedelic therapeutics, to conduct its first-in-human clinical trial of CYB003. This trial is designed to assess the efficacy and safety of CYB003 in patients with MDD and is among the first to evaluate a standardized psychedelic treatment regimen in this patient population.”

About CYB003

CYB003 is derived from 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-HT_{2A} receptor. CYB003 is a deuterated psilocybin analog that has the potential to effectively treat major depressive disorder and alcohol use disorder.

About Clinilabs Drug Development Corporation

Clinilabs Drug Development Corporation is the only global, full-service contract research organization (CRO) 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 21-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.

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, United Kingdom 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.

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 regarding the Company’s proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens to potentially treat psychiatric disorders.

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 December 31, 2021 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. 

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