



Cybin Receives FDA IND Clearance for its Phase 1/2a Clinical Trial Evaluating CYB003 for the Potential Treatment of Major Depressive Disorder

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-- Marks the first novel psilocybin analog to enter clinical development --
-- Patient recruitment to commence immediately --
-- Pharmacokinetic and safety data readout expected in Q4 2022 --

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 received a "may proceed letter" and Investigational New Drug Application ("IND") clearance from the U.S. Food and Drug Administration ("FDA") for its Phase 1/2a first-in-human clinical trial evaluating CYB003. CYB003 is a proprietary deuterated psilocybin analog that is being developed for the potential treatment of major depressive disorder ("MDD"). This milestone marks the industry's first ever novel psilocybin analog to enter clinical development. The Company will begin recruiting patients immediately and expects to provide an interim pharmacokinetic ("PK") and safety data readout in Q4 2022.

"We are extremely pleased to advance CYB003 into clinical development so quickly. Our team has worked diligently to achieve this major regulatory milestone and we look forward to collaborating with Clinilabs, our drug development partner, to accelerate this program," said Doug Drysdale, Chief Executive Officer of Cybin. "This Phase 1/2a trial represents the first time that a psilocybin analog will be evaluated for the treatment of MDD and is the key next step toward our ultimate goal of providing a new and effective treatment for people suffering with mental health conditions."

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 selective serotonin reuptake inhibitors 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 benefit of CYB003 when administered at up to two doses of 12mg and will provide important PK and safety data to determine a clinical path forward. An optional open-label follow-up study will assess 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.

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-HT_{2A} 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.

Preclinical Results for CYB003

In multi-species preclinical studies, CYB003 demonstrated:

- a well-tolerated profile following several doses in multiple species that supports repeat dosing in humans;
- a similar *in vitro* and *in vivo* pharmacology profile when compared to psilocin, the active naturally occurring psychedelic agent in psilocybin;
- a 50% reduction in variability compared to classic psilocybin, indicating the potential for more accurate dosing;
- a 50% dose reduction compared to classic psilocybin, indicating the potential to maintain equivalent efficacy while reducing side effects;
- a 50% shorter time to onset when compared to classic psilocybin, indicating the potential for shorter duration of treatment, lower inter-subject variability, and better therapeutic control; and,

- nearly double the brain penetration when compared to classic psilocybin, indicating the potential for a less variable treatment response.

"Multiple academic studies have shown that psychedelic-based treatments, like psilocybin, may have the potential to revolutionize mental healthcare, but few companies have addressed the well-known limitations and side effects of oral psilocybin. We believe CYB003 has the potential to offer people in need with a more tolerable and potentially more effective treatment option. We look forward to advancing this important compound through clinical development," concluded Drysdale.

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 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 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 plans to start recruiting patients immediately for its CYB003 Phase 1/2a trial, the Company's plans to readout interim PK and safety data by the end of 2022, 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 year ended March 31, 2022 and the Company's annual information form for the year ended March 31, 2022, 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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