



Cybin Receives Institutional Review Board Approval for its Phase 1/2a Clinical Trial Evaluating CYB003 for the Treatment of Major Depressive Disorder

June 9, 2022

-- First-in-human Phase 1/2a trial evaluating the proprietary deuterated psilocybin analog CYB003 expected to begin in mid-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 Institutional Review Board (“IRB”) approval to begin the first-in-human Phase 1/2a clinical trial evaluating CYB003, its proprietary deuterated psilocybin analog, for the treatment of major depressive disorder (“MDD”).

“IRB approval of our trial protocol is a significant regulatory milestone for CYB003 as it leads us one step closer to potentially providing this important treatment option to people in need. The team has worked tirelessly to move this program into the clinic, and we look forward to initiating the study in mid-2022 and further supporting our mission to develop psychedelics into therapeutics,” said Doug Drysdale, Chief Executive Officer of Cybin.

In May 2022, the Company announced that it had submitted an Investigational New Drug application to the U.S. Food and Drug Administration (FDA) for the Phase 1/2a clinical trial. Cybin IRL Limited, a wholly owned subsidiary of Cybin, has engaged Clinilabs Drug Development Corporation, a global, full-service contract research organization with deep expertise in central nervous system drug development, to carry out the Phase 1/2a clinical trial of CYB003.

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. Subjects will receive two administrations (placebo/active and active/active) and a response/remission will be assessed at Week 3 (after single dose) and at Week 6 (after receiving a second dose). 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 more than one administration and will provide pharmacokinetic and safety data. The trial design will allow for people to continue their treatment with selective serotonin reuptake inhibitors (SSRIs). An optional open-label follow-up study (up to 12 weeks) will allow an assessment of durability of treatment effects.

The detailed Phase 1/2a study protocol is available at clinicaltrials.gov under the Identifier number: NCT05385783.

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 designed to achieve less variability in plasma levels, faster onset of action, shorter duration of effect and potentially better tolerability for an overall better outcome for patients. CYB003 has the potential to effectively treat major depressive disorder and alcohol use disorder.

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 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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