Cybin Submits IND Application to FDA for its Phase 1/2a First-in-Human Trial of CYB003 for the Treatment of Major Depressive Disorder

May 31, 2022

-- CYB003 is the first psilocybin analog to be evaluated in Phase 1/2a development for the treatment of major depressive disorder --

TORONTO--(BUSINESS WIRE)-- Cybin Inc. (NEO:CYBN) (NYSE American:CYBN) (**Cybin** or the **Company**), a biopharmaceutical company focused on progressing "Psychedelics to Therapeutics™", is pleased to announce the submission of an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for its Phase 1/2a first-in-human clinical trial evaluating CYB003, a proprietary deuterated psilocybin analog, for the treatment of major depressive disorder ("MDD").

"Following the successful completion of our IND-enabling work just last month, we are very excited to have reached this major milestone toward advancing CYB003 into clinical development so quickly. Based on preclinical studies, our proprietary psilocybin analog has the potential to offer numerous advantages over classic psilocybin with the potential to ultimately provide better outcomes for people suffering with MDD," said Doug Drysdale, Chief Executive Officer of Cybin. "This FDA submission is the next major step in the advancement of CYB003, and we continue to work tirelessly to bring this innovative therapeutic option to people as quickly as possible. We look forward to continuing to work with the FDA to initiate the Phase 1/2a trial in mid-2022."

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 ("PK") 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.

"Through this Phase 1/2a trial, we are primarily looking to demonstrate the improved PK and safety profile of CYB003, as well as efficacy. We have designed the trial to allow people to continue to take their antidepressant medication, which will also allow us to assess the effect of CYB003 on people who are treated with an SSRI. At this time, we expect to have a PK and safety data readout by the end of 2022," concluded Drysdale.

The Company 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.

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-HT2A 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. CYB003 has the potential to effectively treat MDD 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, 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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