Cybin Inc. Announces First Participants Dosed in its Phase 1/2a Trial of CYB003 for the Treatment of Major Depressive Disorder

August 30, 2022

- Clinical milestone marks initiation of first ever novel psilocybin analog to enter clinical development –

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 that the first two participants have been dosed in its Phase 1/2a trial evaluating CYB003 for the treatment of major depressive disorder ("MDD").

"To commence dosing in our first-in-human Phase 1/2a trial is a tremendous milestone for Cybin, especially having reached the clinic within just 18 months. Our goal continues to focus on becoming a leader in creating the best psychedelic therapies for patients and today we have moved one step closer," said Doug Drysdale, Chief Executive Officer of Cybin. "Through our rigorous preclinical work and ongoing clinical development of CYB003, we believe we have the potential to unlock the powerful benefits of psilocybin for the treatment of MDD without its well-known limitations."

"The high level of participant interest in our study serves to validate the significant unmet need for alternative and better treatment options to improve mental health conditions. We expect that this Phase 1/2a trial will provide valuable insights and data. These findings will be critical in establishing a safe and efficacious treatment profile for CYB003 so we can continue to progress our mission to help revolutionize the treatment landscape for people suffering from depression," continued Drysdale.

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. These preclinical data demonstrated that CYB003 has the potential to reduce time and resource burden on patients, providers, and payers, and possibly improve scalability and accessibility of treatment.

Specifically, in multi-species preclinical studies comparing CYB003 with oral psilocybin, data demonstrated:

- a well-tolerated profile following several doses in multiple species that supports repeat dosing;
- 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;
- a 50% dose reduction;
- a 50% shorter time to onset; and,
- nearly double the brain penetration indicating the potential for a less variable treatment response.

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 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.

Cautionary Notes and Forward-Looking Statements

Certain statements in this news release related to the Company are forward-looking statements and are prospective in nature. Forward-looking statements are not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as “may”, “should”, “could”, “intend”, “estimate”, “plan”, “anticipate”, “expect”, “believe” or “continue”, or the negative thereof or similar variations. 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 participants 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 Contact:
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.