



Cybin Completes Dosing in Phase 2 Study of CYB003 for the Treatment of Major Depressive Disorder

October 3, 2023

- *Topline efficacy data expected in Q4 2023* -

- *Preparations are underway to scale the CYB003 program to a potential Phase 3 study in early 2024* -

TORONTO--(BUSINESS WIRE)-- [Cybin Inc.](#) (NYSE American:CYBN) (NEO:CYBN) ("**Cybin**" or the "**Company**"), a clinical-stage biopharmaceutical company committed to revolutionizing mental healthcare by developing new and innovative psychedelic-based treatment options, today announced the completion of dosing of the final cohort in its Phase 2 study of CYB003, a proprietary deuterated psilocybin analog program in development for the potential treatment of major depressive disorder ("MDD"). The CYB003 program is supported by a composition of matter patent with protection through 2041. The Company expects to release topline efficacy data in the fourth quarter of this year.

"We are extremely pleased with the rapid progression we have made from initiation to completion of dosing across all cohorts in our Phase 2 CYB003 MDD study," said Doug Drysdale, Chief Executive Officer of Cybin. "With topline efficacy data expected later this year, we are focusing on the upcoming data submission to the U.S. Food and Drug Administration ("FDA") and readying ourselves to scale for a potential Phase 3 pivotal study early in 2024. We believe this a value inflection point for Cybin, as we continue to pursue our goal of improving the treatment landscape across mental health disorders."

The following doses were evaluated in the six cohorts: 1mg, 3mg, 8mg, 10mg, 12mg, and 16mg. To date, CYB003 has been shown to be safe and tolerable at all doses evaluated with no serious adverse events or discontinuations due to adverse events having been observed in the final dose cohort.

Cybin's preparation for the next stage of development include:

- Commencement of dosing with capsule formulation in the bio equivalence cohort to enable more convenient dosing in Phase 3;
- End of Phase 2 meeting expected in Q1 2024, to review the Phase 3 study design;
- Developing EMBARK for Clinical Trials ("EMBARK^{CT}") as a scalable model of psychedelic facilitation training to support future pivotal studies;
- Partnering with Worldwide Clinical Trials, a global, full-service contract research organization with a successful track record managing clinical trials for mental health conditions, including MDD; and
- Initiating preparations for good manufacturing practices ("GMP") production of a capsule formulation of CYB003 - a robust solid dosage capsule form designed to be stable, dose flexible, patient-friendly, and commercially scalable, to be evaluated in a potential Phase 3 trial.

About the Phase 1/2 CYB003 Trial

The Phase 1/2 trial is a randomized, double-blind, placebo-controlled study evaluating CYB003 in participants with moderate to severe MDD and in healthy volunteers. Healthy volunteers received two administrations (placebo/active and active/active) one week apart, and measures of psychedelic effect are assessed after each dose. Participants with MDD received two administrations (placebo/active and active/active) three weeks apart and response/remission are assessed three weeks after each dose. MDD participants in the trial that are currently being treated with antidepressants are allowed to remain on their antidepressant medication.

The study is evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics, and psychedelic effect of ascending oral doses of CYB003. In participants with MDD, the trial will also assess rapid onset of antidepressant effect on the day of dosing, using the Montgomery-Asberg Depression Rating Scale ("MADRS") and evaluate the incremental benefit of a second dose of CYB003 when administered at Week 3. An optional period of assessment will help determine the durability of treatment effect out to 12 weeks. The study is listed on ClinicalTrials.gov under Identifier: NCT05385783.

About Cybin

Cybin is a clinical-stage biopharmaceutical company on a mission to create safe and effective psychedelic-based therapeutics to address the large unmet need for new and innovative treatment options for people who suffer from mental health conditions.

Cybin's goal of revolutionizing mental healthcare is supported by a network of world-class partners and internationally recognized

scientists aimed at progressing proprietary drug discovery platforms, innovative drug delivery systems, and novel formulation approaches and treatment regimens. The Company is currently developing CYB003, a proprietary deuterated psilocybin analog for the treatment of major depressive disorder and CYB004, a proprietary deuterated DMT molecule for generalized anxiety disorder and has a research pipeline of investigational psychedelic-based compounds.

Headquartered in Canada and founded in 2019, Cybin is operational in Canada, the United States, the United Kingdom, the Netherlands and Ireland. For company updates and to learn more about Cybin, visit www.cybin.com or follow the team on X, LinkedIn, YouTube and Instagram.

Cautionary Notes and Forward-Looking Statements

Certain statements in this news release relating 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 regarding the Company’s plans to report Phase 2 efficacy data from its CYB003 program in Q4 2023; progression to Phase 3 development of CYB003 in early 2024; timing of meeting and submission of data to the FDA in support of a Phase 3 pivotal study; development of EMBARK^{CT} to support future pivotal studies; partnering with Worldwide Clinical Trials in support of clinical trials; preparations for GMP production of a capsule formulation of CYB003; and the Company’s plans 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 spread of COVID-19 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 each of the Company’s management’s discussion and analysis for the year ended March 31, 2023, and the Company’s annual information form for the year ended March 31, 2023, which are available under the Company’s profile on www.sedarplus.ca 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.

Investors & Media:

Gabriel Fahel
Chief Legal Officer
Cybin Inc.
1-866-292-4601
irteam@cybin.com – or – media@cybin.com

Source: Cybin Inc.