Cybin Announces Phase 2 Cohort 5 Dosing Completion of CYB003 in Major Depressive Disorder

July 24, 2023

- Cohort 5 completed with no safety or tolerability issues, Final cohort 6 is recruiting with dosing expected to commence shortly -

- Phase 2 efficacy data for CYB003 in major depressive disorder expected in Q3/Q4 2023 -

- U.S. Food and Drug Administration ("FDA") submission of CYB003 Phase 1/2a data for pivotal studies expected following topline efficacy data readout -

TORONTO--(BUSINESS WIRE)-- Cybin Inc. (NYSE American:CYBN) (NEO:CYBN) ("**Cybin**"), a clinical-stage biopharmaceutical company committed to revolutionizing mental healthcare by developing new and innovative psychedelic-based treatment options, is pleased to announce that its Phase 2 trial evaluating CYB003, an investigational proprietary deuterated analog of psilocybin for the potential treatment of major depressive disorder ("MDD"), has completed dosing in Cohort 5 with no serious adverse events or other adverse events that may preclude continued dosing. The completed Cohorts 4 and 5 evaluated two 12mg doses of CYB003, and recruitment is underway to commence dosing for Cohort 6, the final cohort in the Phase 2 portion of the study.

"The completion of CYB003 dosing in Cohort 5 represents a significant milestone in the progression of our Phase 2 study, taking us one step closer towards establishing a therapeutically efficacious dose and advancing CYB003 towards pivotal studies with the goal of bringing CYB003 as a differentiated and rapid-acting therapeutic option for people with major depressive disorder," said Doug Drysdale, Chief Executive Officer of Cybin. "We are proud of the speed with which we have advanced our clinical-stage programs and remain on track to deliver topline efficacy data from this Phase 2 study later this year and submit data to the FDA in preparation for a potential pivotal study of CYB003."

To date, CYB003 has demonstrated a favorable safety and tolerability profile with no serious adverse events reported at the doses evaluated (1mg, 3mg, 8mg, 10mg, and 12 mg). Interim findings from the Phase 1/2a study have also demonstrated positive observations, showing that CYB003 dosing led to a rapid and robust psychedelic response in participants at low doses, while maintaining a safe and well-tolerated therapeutic profile.

Upcoming milestones for the CYB003 program:

- Completion of CYB003 dosing in MDD cohorts expected in Q3 2023
- Topline efficacy data readout from CYB003 Phase 2 clinical trial expected in Q3/Q4 2023
- U.S. Food and Drug Administration ("FDA") submission of CYB003 Phase 1/2a data for pivotal studies expected following topline efficacy data readout

About the Phase 1/2a CYB003 Trial

The Phase 1/2a trial is a randomized, double-blind, placebo-controlled study evaluating CYB003 in participants with moderate to severe MDD and in healthy volunteers. Per a protocol amendment that was announced on February 28, 2023, the study introduced healthy volunteers for the lower (sub-therapeutic) dose cohorts and added a bioequivalence and food effect cohort to facilitate the transition to pivotal studies. Healthy volunteers receive two administrations (placebo/active and active/active) one week apart, and measures of psychedelic effect are assessed after each dose. Participants with MDD receive 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 will be allowed to remain on their antidepressant medication.

The study will evaluate the safety, tolerability, pharmacokinetics ("PK") and pharmacodynamics ("PD"), 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 (or the "Company") 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 Twitter, 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 anticipated results and potential of CYB003 and the Company's CYB003 Phase 1/2a trial; the Company's plan to report top-line results from the complete CYB003 Phase 2 clinical trial; timing in respect of completion of CYB003 dosing; timing in respect of submission of CYB003 Phase 1/2a data for pivotal studies; 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.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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Source: Cybin Inc.