



Cybin Announces Positive Data from its CYB003 Phase 1/2a Trial and Provides Update on its CYB004 Development Program

February 28, 2023

- CYB003 Phase 1/2a interim data demonstrate rapid and short-acting effects; robust psychedelic effects at low doses; positive safety and tolerability profile; top-line efficacy data expected late Q3 2023 -

- Initial findings from Phase 1 CYB004-E study suggest IV DMT was well-tolerated; study design expanded to accelerate first-in-human dosing of CYB004 -

- Company to host R&D Day webcast today, February 28, 2023, at 10:00am ET -

This news release constitutes a "designated news release" for the purposes of Cybin's prospectus supplement dated August 8, 2022 to its short form base shelf prospectus dated July 5, 2021

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 significant progress updates for its two lead clinical development programs: CYB003, its proprietary deuterated psilocybin analog for the potential treatment of Major Depressive Disorder and CYB004, its proprietary deuterated N,N-dimethyltryptamine molecule being developed for the potential treatment of Generalized Anxiety Disorder. In connection with today's announcement, Cybin will host an R&D Day today, February 28, 2023, at 10:00am ET. To register for the virtual event, [click here](#).

Interim findings from the Company's ongoing Phase 1/2a clinical trial evaluating CYB003 demonstrated positive observations, including a rapid and short-acting psychedelic response in participants. Participants received single oral doses of CYB003 at 1 milligram ("mg"), 3mg, 8mg, and 10mg, respectively, and all doses were well-tolerated with no serious adverse events reported. Most notably, participants reported meaningful and robust psychedelic effects at the 8mg and 10mg doses, confirming a complete mystical experience was achieved. These interim findings demonstrate that CYB003 was rapid and short acting, had low variability in plasma levels, and reached a psychedelic effect at low doses, while maintaining a safe and well-tolerated therapeutic profile. As of the date of this press release, Phase 1 dosing has been completed and the Phase 2a portion of the trial has commenced. Cybin expects to report top-line results from the completed Phase 1/2a clinical trial in late third quarter of calendar year 2023.

"It is incredibly gratifying that our findings from the interim readout of the CYB003 Phase 1/2a clinical trial align with the results observed in preclinical studies. Robust psychedelic effects were observed at low doses, absorption was rapid with low variability, and effects were short lasting – all desired outcomes. These findings give us confidence in the potential efficacy of the underlying active agent, which may ultimately reduce symptoms of depression after just one or two doses. This would be a remarkable improvement over chronic treatments that are available today," said Doug Drysdale, Chief Executive Officer of Cybin. "We are encouraged by the progress made in advancing our CYB003 molecule and look forward to continuing the momentum to advance this program through clinical development to bring this important treatment option to people who suffer from depression as quickly as possible."

The Company today also provided an update on its Phase 1 CYB004-E trial evaluating intravenous N,N-dimethyltryptamine ("IV DMT") in healthy volunteers. Per a protocol amendment to the initial trial design, Cybin has established a three-part study to include Part A (IV DMT infusion), Part B (IV DMT bolus + infusion) and Part C (CYB004) in healthy volunteers, which will allow the Company to initiate first-in-human dosing of CYB004 sooner than initially planned. Data from the new Parts B and C of the trial will serve to build a more robust pharmacokinetic ("PK") and pharmacodynamic ("PD") model to optimize dose selection and formulation development for future clinical studies. The Company confirmed today that Part A of the trial evaluating DMT IV in participants is now complete, and IV DMT at the evaluated dose ranges was demonstrated to be safe and well-tolerated. As of the date of this press release, the Phase 1 CYB004-E trial has dosed 40 participants in Part A and dosing has commenced in Part B. Dosing of CYB004 in Part C is expected to begin in early Q2 2023, following the completion of Part B. Cybin expects to report top-line results from the completed Phase 1 CYB004-E clinical trial in the third quarter of calendar year 2023.

"Our CYB004 program has made significant progress marked by confirmatory results from Part A of the Phase 1 CYB004-E trial and the acceleration of first-in-human dosing of CYB004," continued Drysdale. "Recent protocol amendments will allow us to further evaluate CYB004 and demonstrate the advantages of deuteration on PK and PD parameters. We see the potential for short duration treatments, which could truly transform the treatment paradigm and outcomes for patients. As well, we believe that deuteration may support less invasive and more convenient dosing methods for providers and patients."

R&D Day to be held today February 28, 2023, at 10:00 a.m. ET.

Cybin's leadership team is hosting a virtual R&D Day event today, featuring key opinion leader Dr. Maurizio Fava, Psychiatrist-in-Chief of Massachusetts General Hospital ("MGH"), Vice Chair of the MGH Executive Committee on Research, Executive Director of the Clinical Trials Network and Institute at MGH, Associate Dean for clinical and translational research, and the Slater Family Professor of Psychiatry at Harvard Medical School. The Company will provide further information on the interim readout from its ongoing CYB003 Phase 1/2a trial and additional updates on its CYB004 program. [Click here](#) to register for the event.

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 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 1/2a clinical trial; the Company's plan to report top-line results from the complete Phase 1 CYB004-E clinical trial; statements regarding the Company's Phase 1 DMT clinical study for CYB004-E, anticipated results and the impact of this study on future clinical trials; the Company's clinical development program evaluating CYB004 and timeline for dosing healthy volunteers; 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 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 each of the Company's management's discussion and analysis for the three and nine month periods ended December 31, 2022, the Company's annual information form for the year ended March 31, 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. 

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