



Cybin Initiates First-in-Human Dosing of CYB004 in Phase 1 Clinical Trial

May 24, 2023

- CYB004, a deuterated dimethyltryptamine (“dDMT”) molecule, has potential to overcome existing limitations of DMT and is protected by a composition of matter patent through 2041 –

-- Parts A and B of Phase 1 study complete; Part C to determine safety, pharmacokinetic (“PK”) and pharmacodynamic (“PD”) of escalating doses of CYB004 in healthy volunteers --

- Phase 1 topline safety and efficacy data expected in Q3 2023 -

TORONTO--(BUSINESS WIRE)-- [Cybin](#) Inc. (NEO:CYBN) (NYSE American: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 that the first participants have been dosed with CYB004 in its ongoing three-part Phase 1 clinical trial evaluating intravenous N,N-dimethyltryptamine (“IV DMT”) and CYB004 in healthy volunteers. As expected, robust psychedelic effects were seen within two minutes, reaching a peak at about thirteen minutes. No safety concerns were reported from these initial participants.

“The first-in-human dosing of CYB004 represents an enormous step forward in the clinical advancement of our program evaluating this innovative compound for the potential treatment of Generalized Anxiety Disorder,” said Doug Drysdale, Chief Executive Officer of Cybin. “The inclusion of CYB004 dosing in our Phase 1 trial affords us the opportunity to better understand the PK/PD profile of CYB004 and validate the advantages of this proprietary molecule in humans earlier than expected. We plan to leverage these findings to support our goal of developing a differentiated psychedelic-based therapeutic with an optimal treatment profile that may offer less invasive and more convenient dosing methods to provide new and improved treatment options for patients and providers.”

Part C of the Phase 1 CYB004-E trial is a crossover study design which will evaluate IV bolus + infusion regimens of CYB004 in up to two cohorts. Data from Part C and the completed Part B portion of the Phase 1 study are expected to provide a comprehensive PK and PD model that will be used to determine optimal dosing and formulation for future clinical trials of CYB004. The Company anticipates a topline data readout from the Phase 1 trial in the third quarter of calendar year 2023.

“We are proud of the speed in which we have advanced this CYB004 program and look forward to sharing topline results later this year, along with additional topline efficacy data from our lead clinical program, CYB003, which is currently being studied in patients with Major Depressive Disorder,” concluded Drysdale.

About the CYB004-E Phase 1 Trial

The Phase 1 trial is a three-part study evaluating the safety, pharmacokinetics, and pharmacodynamics of escalating doses of DMT and CYB004 in healthy volunteers. The three-part study design was established in a protocol amendment to the initial study design, allowing the Company to initiate first-in-human dosing of CYB004 sooner than initially planned. The CYB004-E study is being conducted at the Centre for Human Drug Research in the Netherlands and is one of the largest Phase 1 DMT clinical trials to date.

About CYB004

CYB004 is a proprietary deuterated DMT molecule. DMT has been shown to exert its psychedelic effects by activating the 5-HT_{2A} receptor. In its regular form, DMT is an unstable molecule rapidly metabolized in the body, which significantly reduces its bioavailability. By maximizing CYB004 as a deuterated molecule and improving upon the bioavailability of DMT, CYB004 has the potential to overcome existing limitations of DMT and offer less invasive and more convenient dosing methods.

CYB004 is being evaluated as a potential treatment for Generalized Anxiety Disorder with or without Major Depressive Disorder. CYB004 is secured by a U.S. composition of matter patent with protection through 2041. The patent covers a range of deuteration forms of DMT and protects CYB004 as a putative new chemical entity.

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 Twitter, LinkedIn, YouTube and Instagram.

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 expectations and objectives regarding the results of the CYB004-E study, the Company's plan to report top-line results from the complete Phase 1 CYB004-E clinical trial, the Company's clinical development program evaluating CYB004, the Company's future clinical trials; and the Company's plans to engineer proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and therapy 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 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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