



Cybin Announces Successful Completion of In Vivo Preclinical Studies for its Deuterated Psilocybin Analog CYB003 Supporting Advancement into Phase 1/2a Clinical Trial

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-- IND-enabling safety pharmacology and toxicology studies completed in multiple species under GLP guidelines -

- On track to submit IND to U.S. FDA in Q2 2022 for expected initiation of Phase 1/2a trial in mid-2022 --

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 report the completion of *in vivo* preclinical studies evaluating its deuterated psilocybin analog CYB003 for the potential treatment of major depressive disorder (MDD). Data from *in vivo* preclinical studies demonstrate that CYB003 is well-tolerated following several doses in multiple species and support the advancement toward an investigational new drug ("IND") filing with the U.S. Food and Drug Administration ("FDA") for a Phase 1/2a first-in-human clinical trial in patients with MDD. The preclinical *in vivo* studies followed FDA protocol and were completed under Good Laboratory Practice ("GLP") guidelines.

"The completion of these *in vivo* preclinical studies for CYB003 represents a significant milestone toward advancing this program into first-in-human clinical development and brings us one step closer to progressing CYB003 as a best-in-class treatment candidate for mental illness and addiction. We plan to focus the Phase 1/2a trial in the United States. We believe this will allow us to escalate the study through early-stage clinical development and into a potential broader Phase 2b trial, while concurrently collecting a large amount of data to support late-stage studies," said Doug Drysdale, Chief Executive Officer of Cybin.

"We are excited to complete this integral step toward moving CYB003 into the clinic – an impressive journey that took less than 18 months since discovery of the CYB003 molecule. Based on its attractive preclinical profile and the ability to translate these results in patients, we believe that CYB003 has the potential to be a novel and effective treatment for the many people suffering from MDD," said Dr. Amir Inamdar, Chief Medical Officer of Cybin.

Preclinical Study Results:

In multi-species preclinical studies, CYB003 demonstrated:

- a well-tolerated profile following several doses in multiple species that supports repeat dosing in humans;
- 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 compared to classic psilocybin, indicating the potential for more accurate dosing;
- a 50% dose reduction compared to classic psilocybin, indicating the potential to maintain equivalent efficacy while reducing side effects;
- a 50% shorter time to onset when compared to classic psilocybin, indicating the potential for shorter duration of treatment, lower inter-subject variability, and better therapeutic control; and
- nearly double the brain penetration when compared to classic psilocybin, indicating the potential for a less variable treatment response.

The Company plans to submit an IND to the FDA in the second quarter of 2022 and to initiate the Phase 1/2a clinical trial in mid-2022.

About CYB003

CYB003 is derived from psilocybin, which is part of a family of molecules called indolamines that include more common neurotransmitters, such as serotonin. Psilocybin is dephosphorylated to form its metabolite, psilocin, which can cross the blood-brain-barrier. Given its structural similarity to serotonin, psilocin can easily activate the serotonin 5-HT_{2A} receptor. CYB003 is a deuterated psilocybin analog designed to achieve less variability in plasma levels, faster onset of action, shorter duration of effect and potentially better tolerability for an overall better outcome for patients. CYB003 has the potential to effectively treat major depressive disorder (MDD) and alcohol use disorder (AUD).

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, United Kingdom 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 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 proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens to potentially treat psychiatric disorders.

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 December 31, 2021 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.

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