



Cybin Announces Approval of First-in-Human Dosing of its Proprietary DMT Molecule CYB004

February 1, 2023

- Marks first ever trial to evaluate deuterated DMT in humans –

- Based on preclinical studies CYB004 demonstrated superior bioavailability compared to IV DMT which may support less invasive dosing methods -

- CYB004 is a patented proprietary molecule protected through 2041 -

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 announce that it has received approval from an independent ethics committee in the Netherlands to initiate first-in-human dosing of its proprietary deuterated N,N-dimethyltryptamine ("**DMT**") molecule CYB004 through a protocol amendment to its ongoing CYB004-E Phase 1 trial. This clinical advancement marks the first time a deuterated DMT molecule will be evaluated in humans and further reduces Cybin's time-to-clinic with CYB004.

The Phase 1 CYB004-E trial is being conducted at the Centre for Human Drug Research in the Netherlands and is the largest ever Phase 1 DMT trial conducted to-date.

In its regular form, DMT is an unstable molecule rapidly metabolized in the body, which significantly reduces its bioavailability. CYB004 has the potential to overcome the limitations of DMT. Based on preclinical studies, CYB004 has demonstrated an improved bioavailability and pharmacokinetic profile in comparison to DMT when administered via intravenous ("**IV**") and inhaled routes. These studies also demonstrated that IV CYB004 has a longer duration of effect compared to DMT, indicating the potential to extend the therapeutic window and provide better dose optimization. By maximizing CYB004 as a deuterated molecule and improving upon the bioavailability of DMT, CYB004 has the potential to offer more convenient dosing methods via inhaled, subcutaneous, or intramuscular routes of administration.

"This is a major milestone for our CYB004 program and for better understanding the potential therapeutic benefits of our proprietary deuterated DMT molecule for the treatment of generalized anxiety disorder," said Doug Drysdale, Cybin's Chief Executive Officer. "The ability to evaluate our novel CYB004 molecule in humans at this early stage is a significant achievement in clinical development and will provide important insight into the pharmacokinetic and pharmacodynamic properties of CYB004 in addition to what we have already learned through our study of DMT. We expect to apply these findings to optimize dosing and delivery of CYB004 in future clinical trials, which supports our mission to bring this new investigational therapy to patients as quickly as possible."

Cybin secured a U.S. composition of matter patent covering CYB004 in February 2022 that provides patent protection through 2041. The patent covers a range of deuterated forms of DMT and protects CYB004 as a putative new chemical entity.

"With strong intellectual property in place and promising preclinical data, we believe we have a solid clinical development path forward for CYB004. We will continue to focus our research on identifying the most convenient routes of administration while also maintaining an optimal therapeutic profile for this important molecule," concluded Drysdale.

The Company plans to evaluate CYB004 for the treatment of generalized anxiety disorder with or without major depressive disorder.

Cybin will provide additional information on its CYB004 program, including an update on the Phase 1 CYB004-E trial, at its upcoming virtual R&D Day on February 28, 2023. 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 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 related to the results of the Company's CYB004 pre-clinical studies, statements regarding the Company's expectations and objectives regarding the results of the CYB004-E study, and the Company's proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens to potentially treat generalized anxiety disorder with or without major depressive disorder and/or other 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 three and six month periods ended September 30, 2022 and the Company's annual information form for the year ended March 31, 2022, 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 or nutraceutical products. 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 or nutraceuticals can diagnose, treat, cure or prevent any disease or condition. Vigorous 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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