



Cybin Outlines Upcoming Priorities and Milestones for its Clinical Development Programs

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TORONTO--(BUSINESS WIRE)-- [Cybin Inc.](#) (NEO:CYBN) (NYSE American: CYBN) (**Cybin** or the **Company**), a biopharmaceutical company focused on progressing Psychedelics to Therapeutics® today outlined its upcoming priorities and near-term milestones that support the development of its CYB003 and CYB004 clinical programs aimed at addressing multiple mental health conditions.

"Cybin enters 2023 with the potential to reach a number of value-driving milestones, including important advancements across our development pipeline," said Doug Drysdale, Chief Executive Officer of Cybin. "These priorities will provide important information to help strengthen our business as we continue to focus on the progression of our innovative investigational therapies aimed at addressing the significant unmet need for people struggling with mental health conditions."

CYB003 for the Treatment of Major Depressive Disorder ("MDD")

Cybin is currently conducting a Phase 1/2a clinical trial evaluating CYB003, a deuterated psilocybin analog, in people suffering from MDD. The Company today announced that it plans to provide an interim readout from the Phase 1/2a trial by the end of February 2023. The interim readout is intended to provide an initial understanding of the safety and pharmacokinetic ("PK") profile of CYB003 in humans, including preliminary observations related to the psychedelic effect and duration of psychedelic effect of CYB003. These findings will help provide the necessary dose ranging information for the ongoing Phase 1/2a trial in addition to future clinical studies evaluating CYB003.

CYB003 is designed to potentially address the challenges and limitations of oral psilocybin. Based on preclinical data, CYB003 achieved less variability in plasma levels, faster onset of action, and shorter duration of effect. CYB003's therapeutic profile as a differentiated treatment for MDD is expected to provide more consistent and predictable dosing, and reduced intra- and inter-individual variability, ultimately resulting in reduced time and resource burden on the healthcare system.

CYB003 is the first ever deuterated psilocybin analog to enter clinical development.

CYB004 for the Treatment of Anxiety Disorders

Cybin is currently conducting a Phase 1 exploratory trial ("CYB004-E trial") evaluating IV N,N-dimethyltryptamine ("DMT") to yield essential safety and dosing optimization data for the future clinical development of CYB004 (deuterated DMT) for the treatment of anxiety disorders. To date, the CYB004-E trial has not demonstrated any clinically significant safety or tolerability issues. Cybin expects to translate key learnings from the initial study, including dose optimization and dosing dynamics, to support the remaining planned cohorts. These learnings are also expected to accelerate Cybin's plans to commence dosing of CYB004 in humans. The Company plans to provide an update on its CYB004 program by the end of February 2023.

In its natural form DMT is rapidly metabolized in the body and is not orally bioavailable. Based on preclinical studies, CYB004, a new chemical entity, has the potential to overcome the limitations of DMT. Specifically, these data showed that CYB004 had increased oral and pulmonary bioavailability, faster onset with lower doses, lower inter-subject variability, and better dose titration for fewer side effects compared with oral and IV DMT.

Cybin secured a U.S. composition of matter patent covering CYB004 in February 2022.

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 regarding the anticipated results and potential of the Company’s CYB003 Phase 1/2a trial; the Company’s plans to provide an interim safety and PK readout from the Phase 1/2a study in early 2023; statements regarding the Company’s CYB004-E Phase 1 DMT clinical study and anticipated results; and the Company’s plan to engineer proprietary drug development 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 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.

Neither the Neo Exchange Inc. nor the NYSE American LLC stock exchange have approved nor disapproved the contents of this news release and are not responsible for the adequacy and accuracy of the contents herein. 

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