Cybin Announces FDA Clearance to Initiate a Phase 2a Study of CYB004 in Generalized Anxiety Disorder

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- Recently announced positive Phase 1 topline safety, pharmacokinetic ("PK") and pharmacodynamic ("PD") data show that intravenous ("IV") CYB004 demonstrated robust and rapid-onset psychedelic effects at lower doses compared to native DMT -

- U.S. composition of matter patent granted with protection expected through 2041 -

- Company to initiate a randomized, double-blind, active controlled Phase 2a study in Q1 2024 -

TORONTO--(BUSINESS WIRE)-- Cybin Inc. (NYSE American:CYBN) (Cboe CA:CYBN) ("**Cybin**" or the " **Company**"), a clinical-stage biopharmaceutical company committed to revolutionizing mental healthcare by developing new and innovative next-generation psychedelic treatment options, today announced that the U.S. Food and Drug Administration ("FDA") has cleared its investigational new drug ("IND") application for CYB004, its proprietary deuterated dimethyltryptamine ("DMT") molecule in development for the treatment of Generalized Anxiety Disorder ("GAD"). This clearance allows the Company to proceed with its plans to initiate a Phase 2a study of CYB004 in Q1 2024. The Phase 2a study will be a randomized, double-blind, active-controlled trial to assess the preliminary clinical efficacy, safety, tolerability, PK and PD of CYB004 in participants with GAD. This trial will be conducted at study sites in the United States.

"With the recent positive topline results from two Phase 1 studies of our proprietary deuterated DMT molecules, CYB004 and SPL028, we are well-positioned to initiate a Phase 2a study of CYB004 in GAD this quarter," said Doug Drysdale, Chief Executive Officer of Cybin. "From our extensive portfolio of DMT and deuterated DMT datasets across five completed clinical studies, we have gathered important insights on dosing and preliminary efficacy signals in both depression and anxiety that will inform our next steps. Exploratory data from our completed Phase 2a study of SPL026 (IV DMT) have shown that SPL026 reduced symptoms of anxiety in patients with major depressive disorder, which further serves to de-risk the development of deuterated DMT in anxiety disorders as we continue to evaluate the efficacy and safety of CYB004."

"Although anxiety disorders are one of the most prevalent mental health disorders, current treatment options remain limited, with suboptimal response and remission rates. We are committed to developing improved treatment options with the goal of improving the quality of life for people suffering from anxiety disorders worldwide. We look forward to exploring the potential of CYB004 to offer more convenient and patient-friendly dose forms and treatment duration," concluded Drysdale.

About Generalized Anxiety Disorder

Anxiety disorders are the most prevalent mental health disorders globally[1], contributing to over 28 million disability-adjusted life years (DALYs).[2] GAD is the most common anxiety disorder seen in primary care, with a 12-month prevalence of 2.9% in the United States.[3]

Sources

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2. Yang X., Fang Y., Chen H., Zhang T., Yin X., Man J., Yang L., Lu M. (2021). Global, regional and national burden of anxiety disorders from 1990 to 2019: results from the Global Burden of Disease Study 2019. *Epidemiology and Psychiatric Sciences* 30, e36, 1–11. https://doi.org/10.1017/S2045796021000275
3. Ansara E. D. (2020). Management of treatment-resistant generalized anxiety disorder. The mental health clinician, 10(6), 326–334. https://doi.org/10.9740/mhc.2020.11.326

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 X, LinkedIn, YouTube and Instagram.

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 Company’s plans to initiate a Phase 2a study of CYB004 in Q1 2024; the Company’s expectations from the Phase 2a study of SPL026 to de-risk the development of deuterated DMT; and the Company’s proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health 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 spread of COVID-19 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 six month periods ended September 30, 2023, and the Company’s annual information form for the year ended March 31, 2023, which are available under the Company's profile on SEDAR+ at www.sedarplus.ca 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 Cboe CA 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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