



Cybin Confirms Scientific Advice Meeting with UK Medical and Healthcare Products Regulatory Agency for Lead Candidate CYB003 for the Treatment of Major Depressive Disorder and Alcohol Use Disorder

December 8, 2021

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 confirmed a scientific advice meeting with the UK Medical and Healthcare Products Regulatory Agency ("**MHRA**") for the first quarter of calendar year 2022. This program milestone brings the Company closer toward advancing its lead investigational candidate CYB003 into clinical development for the treatment of major depressive disorder ("**MDD**") and alcohol use disorder ("**AUD**").

"Encouraged by positive preclinical findings that demonstrated the advantages of our novel deuterated psilocybin analog over oral psilocybin for the treatment of mental health, we are moving rapidly to progress CYB003 toward clinical development. We are looking forward to engaging with the MHRA to determine next steps for our clinical development path evaluating CYB003 for the treatment of MDD and AUD in the UK," said Doug Drysdale, Chief Executive Officer of Cybin.

"CYB003 was designed to address the shortcomings of existing treatments, while retaining the therapeutic benefits of oral psilocybin. We believe that CYB003 has the potential to achieve better patient outcomes, including less variability, faster onset of action, shorter duration of effect, and improved brain penetration. As a society, we need to prioritize the treatment of mental health, and Cybin is committed to taking these next important steps toward progressing psychedelics to therapeutics," concluded Drysdale.

On November 8, 2021, the Company reported preclinical data for CYB003 demonstrating:

- a 50% reduction in variability compared to oral psilocybin; indicates potential for more accurate dosing in patients with MDD and AUD;
- a 50% reduction in dose compared to oral psilocybin; indicates potential to maintain equivalent efficacy while reducing side effects, such as nausea, in patients with MDD and AUD;
- a 50% shorter time to onset when compared to oral psilocybin; indicates potential for shorter duration of treatment, lower inter-subject variability, better therapeutic control and safety, leading to a better patient experience, with lower cost and scalability; and
- nearly double brain penetration when compared to oral psilocybin; indicates potential for a less variable treatment response, a lower dose therapeutic effect, and reduced patient side effects.

The Company plans to file a clinical trial application with the MHRA in the second quarter of calendar year 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 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 September 30, 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.

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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Source: Cybin Inc.