



Cybin Selects Generalized Anxiety Disorder as Target Indication for Deuterated DMT Molecule CYB004

January 12, 2023

TORONTO--(BUSINESS WIRE)-- [Cybin Inc.](#) (NEO: CYBN) (NYSE American: CYBN) (**Cybin** or the **Company**), a biotechnology company focused on progressing Psychedelics to Therapeutics® today announced that it has selected Generalized Anxiety Disorder ("GAD") with or without major depressive disorder ("MDD") as the target indication for its proprietary deuterated N, N-dimethyltryptamine ("DMT") molecule, CYB004.

"Based on preclinical data, CYB004 has shown promise in treating anxiety disorders. About half of people suffering from depression are also burdened with GAD, which makes the need for more effective treatment options for GAD even more urgent," said Doug Drysdale, Chief Executive Officer of Cybin. "Since the pandemic, the prevalence of depression and anxiety has been significantly elevated, and we are optimistic that through our current development programs, Cybin has the potential to provide innovative therapeutics to alleviate the mental suffering that so many people experience worldwide. We remain focused on the opportunity that CYB004, as a new chemical entity, may be able to provide a new path toward mental healing."

Generalized anxiety disorder is characterized by excessive worry and tension that is not restricted to any specific environmental circumstances. Anxiety disorders are the most common mental health concern in the United States. Over 40 million adults in the U.S. (19.1% of the total U.S. population) have an anxiety disorder.¹

Additional Facts about Anxiety and Generalized Anxiety Disorder:

- Among psychiatric disorders, GAD and MDD are the leading contributors to global disability. The presence of both GAD and MDD is strongly associated with a poor prognosis, an increase in severe symptoms, poorer quality of life, greater MDD recurrence, and a higher suicide risk than either disorder alone.²⁻⁵
- GAD affects 6.8 million adults, or 3.1% of the U.S. population, in any given year.⁶
- Women are twice as likely to be affected by GAD.⁶
- Worldwide, GAD affects 14.7 million people in any given year.⁷
- 23 % of adults prescribed an SSRI discontinued medication at 4 weeks and 36.5 % within 3 months. Another report indicated that approximately one half of patients discontinued antidepressant medication within 3 months.⁸
- There is a lifetime morbidity risk for GAD, with around 9% prevalence.⁹
- Based on a 2022 Generalized Anxiety Disorder Therapeutics Market Report, the economic burden of GAD is expected to grow to US\$12 billion by 2030.¹⁰

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 for the treatment of GAD. 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 cohorts, including dose optimization and dosing dynamics, to support the remaining planned cohorts in the trial. These learnings are also expected to accelerate Cybin's plans to commence dosing of CYB004 in humans.

In its natural form DMT is rapidly metabolized in the body and is not orally bioavailable. Based on preclinical studies, CYB004 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, low inter-subject variability, and better dose titration for potentially fewer side effects compared with oral and IV DMT.

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

The Company plans to provide an update on its CYB004 program by the end of February 2023.

1. <https://www.nami.org/About-Mental-Illness/Mental-Health-Conditions/Anxiety-Disorders>
2. GBD 2019 (2020). Diseases and Injuries Collaborators. Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet*, 396(10258):1204–22.
3. Zhou Y, Cao Z, Yang M, et al. (2017). Comorbid generalized anxiety disorder and its association with quality of life in patients with major depressive disorder. *Sci Rep.*, 7(1):40511. doi: 10.1038/srep40511.
4. McIntyre RS, Woldeyohannes HO, Soczynska JK, et al. (2016). The prevalence and clinical characteristics associated with diagnostic and statistical manual version-5-defined anxious distress specifier in adults with major depressive disorder: results from the international mood disorders collaborative project. *Ther Adv Chronic Dis.*, 7(3):153–159. doi:

10.1177/2040622315627805.

5. Gaspersz R, Nawijn L, Lamers F, Penninx B (2018). Patients with anxious depression: overview of prevalence, pathophysiology and impact on course and treatment outcome. *Curr Opin Psychiatry*, 31(1):17–25.
6. <https://adaa.org/understanding-anxiety/generalized-anxiety-disorder-gad>
7. GlobalData, Pharma Intelligence Center, Epidemiology & Market Size Database. Based on peer-reviewed literature, disease registries, and primary research.
8. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3024727/>
9. Kessler, R. C., Petukhova, M., Sampson, N. A., Zaslavsky, A. M., & Wittchen, H. U. (2012). Twelve-month and lifetime prevalence and lifetime morbid risk of anxiety and mood disorders in the United States. *International journal of methods in psychiatric research*, 21(3), 169-184.
10. <https://www.globenewswire.com/en/news-release/2022/10/27/2542715/0/en/Generalized-Anxiety-Disorder-Therapeutics-Market-Report-2022-to-2030-Abbvie-Inc-Pfizer-Inc-Eli-Lilly-and-Company-GSK-PLC-Abbott-Laboratories-Inc-and-Johnson-Johnson.html>

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 CYB004 program, CYB004-E Phase 1 DMT clinical study and anticipated results; the Company's expected timeline to provide an update on its CYB004 program, 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.

Investors & Media:

Leah Gibson
Vice President, Investor Relations & Strategic Communications
Cybin Inc.
irteam@cybin.com - or - media@cybin.com

Gabriel Fahel
Chief Legal Officer
Cybin Inc.
1-866-292-4601

Source: Cybin Inc.