



Cybin Receives Australian Approval for EMBRACE, a Multinational Pivotal Study Evaluating CYB003 for the Adjunctive Treatment of Major Depressive Disorder

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- EMBRACE, the second study within the CYB003 Phase 3 PARADIGM program, will enroll 330 participants at approximately 60 clinical sites across the United States, Europe and Australia -
- Recently cleared to initiate the EMBRACE study in Ireland, Poland, Greece, and the United Kingdom -
- Patient dosing continues in APPROACH, the first Phase 3 study, and patient rollover into EXTEND long-term extension study is ongoing -
- Data from completed Phase 2 MDD study showed that 71% of participants were in remission and 100% of participants responded to treatment at 12 months after just two 16 mg doses of CYB003 -

TORONTO--(BUSINESS WIRE)--Aug. 26, 2025-- [Cybin Inc.](#) (NYSE American:CYBN) (Cboe CA:CYBN) ("Cybin" or the "Company"), a clinical-stage breakthrough neuropsychiatry company committed to advancing mental healthcare by developing new and innovative next-generation treatment options, today announced that it has received approval in Australia to conduct the EMBRACE® study. EMBRACE is the second pivotal study in PARADIGM™, the Company's Phase 3 multinational program evaluating CYB003, a proprietary deuterated psilocin analog. The Company has received approval through the Clinical Trial Notification scheme, obtained clearance from multiple Ethics Committees of the Australian Therapeutics Goods Administration, and the study site Research Governance Offices, thus allowing the commencement of the EMBRACE study.

This approval follows two other recent regulatory decisions:

- The Irish Medicines Board, acting as the reference Member state, granted approval to initiate the EMBRACE study in Ireland, Poland, and Greece; and
- The United Kingdom Medical and Healthcare Products Regulatory Agency approved the commencement of the EMBRACE study in the United Kingdom.

CYB003 has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for the adjunctive treatment of Major Depressive Disorder ("MDD").

"Having been granted approval in Australia to commence the EMBRACE component of PARADIGM, we are now cleared to study CYB003 on three continents," said Doug Drysdale, Chief Executive Officer of Cybin. "Initiating the second pivotal study represents an important milestone as we advance and broaden this important clinical program. EMBRACE is a three-arm study with a high dose, mid-dose, and placebo arm. The study aims to enroll 330 participants with moderate to severe MDD and whose symptoms are inadequately controlled with current antidepressants. We are eager to build on the extraordinary 12-month Phase 2 results which showed robust 12-month improvements in depression symptoms after two 16 mg doses of CYB003. Validation from these international regulatory bodies is highly encouraging as we pursue our mission of revolutionizing mental healthcare by developing safe and effective treatments for a variety of mental health conditions."

EMBRACE Study Design:

- EMBRACE will enroll 330 patients with moderate to severe MDD (MADRS≥24) who are on a stable dose of antidepressant medication but are responding inadequately. Study participants will be randomized 1:1:1 to receive either CYB003 16 mg, CYB003 8 mg, or inactive placebo. Each study arm will evaluate two doses, administered three weeks apart.
- The primary endpoint will be change in depressive symptoms as measured by change in MADRS from baseline at six weeks after the first dose.

The Phase 3 PARADIGM program is expected to enroll a total of 550 participants across three studies: two 12-week randomized, double-blind, placebo-controlled studies, APPROACH® and EMBRACE, and a long-term extension study, EXTEND. The first Phase 3 trial, APPROACH, is currently dosing and is taking place at approximately 45 clinical sites across the U.S. The second Phase 3 trial, EMBRACE, is expected to enroll participants at approximately 60 clinical sites across the U.S., Europe, and Australia. Participants from APPROACH and EMBRACE will have the opportunity to roll over into EXTEND after completing the 12-week, double-blind, placebo-controlled treatment periods.

About Cybin

Cybin is a late-stage breakthrough neuropsychiatry company committed to revolutionizing mental healthcare by developing new and innovative next-generation treatment options to address the large unmet need for people who suffer from mental health conditions.

With promising proof-of-concept data, Cybin is working to change the mental health treatment landscape through the introduction of intermittent treatments that provide long lasting results. The Company is currently developing CYB003, a proprietary deuterated psilocin analog, in Phase 3 studies for the adjunctive treatment of major depressive disorder and CYB004, a proprietary deuterated N, N-dimethyltryptamine molecule in a Phase 2 study for generalized anxiety disorder. The Company also has a research pipeline of investigational, 5-HT-receptor focused compounds.

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 or forward-looking information within the meaning of applicable securities laws (collectively, "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", "potential", "possible", "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 enroll 330 participants at 60 clinical sites across the United States, Europe and Australia for the EMBRACE study; enrollment of 550 participants across three studies for the Phase 3 PARADIGM program; and the Company's plans to engineer proprietary drug discovery 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: 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; implications of disease outbreaks on the Company's operations; and the risk factors set out in each of the Company's management's discussion and analysis for the three months ended June 30, 2025 and the Company's annual information form for the year ended March 31, 2025, 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/edgar. 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 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 psilocin, 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 psilocin, 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. 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 Cboe Canada, 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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