Cybin Receives UK MHRA Approval to Commence EMBRACE, A Multinational Pivotal Study Evaluating CYB003 for the Adjunctive Treatment of Major Depressive Disorder

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- EMBRACE, the second Phase 3 study within the PARADIGM program, expects to enroll 330 participants at approximately 60 clinical sites across the United States, Europe and Australia and will commence imminently -

- PARADIGM™ comprises two 12-week randomized, double-blind, placebo-controlled studies (APPROACH® and EMBRACE®) and a long-term extension study (EXTEND), with anticipated combined enrollment of approximately 550 participants –

- Dosing is currently underway in the first pivotal study, APPROACH, and patient rollover has begun into EXTEND -

TORONTO--(BUSINESS WIRE)-- 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 from the UK Medical and Healthcare Products Regulatory Agency ("MHRA") to commence EMBRACE, the second pivotal study in PARADIGM, the Company's Phase 3 multinational program evaluating CYB003, a proprietary deuterated psilocin analog. The Company previously received Breakthrough Therapy Designation from the U.S. Food and Drug Administration ("FDA") for CYB003 for the adjunctive treatment of Major Depressive Disorder ("MDD").

"MHRA approval to initiate the EMBRACE component of our PARADIGM program in the UK marks an important step forward as we advance our lead program, CYB003, through the regulatory process," said Doug Drysdale, Chief Executive Officer of Cybin. "The Agency's decision serves as strong validation of both the quality of our data and the urgent need to develop new and effective therapeutics to treat depression. With expected enrollment of 330 participants suffering from moderate to severe MDD, the EMBRACE study aims to generate critical late-stage data that, ultimately, may lead to transforming the standard of care for patients in need."

"There are encouraging signs of clinical and commercial success across this sector, along with increasing political and regulatory support. Health expert Dr. Martin Makary, Commissioner of the U.S Food and Drug Administration, has publicly recognized the potential value of these innovative therapeutics and has stated his intention to prioritize and expedite the review process. The commercial success of esketamine is also a positive signal for the entire sector. In the second quarter of 2025, esketamine sales totaled $366 million in the U.S. and $414 million worldwide, representing 61.1% growth year over year in the U.S., and an annual run rate of roughly $1.7 billion.[1] These positive factors contribute to the credibility and opportunity of the work we are doing at Cybin," concluded Drysdale.

EMBRACE ™ Study Design:

- EMBRACE will enroll 330 patients suffering from 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.

EMBRACE is the second Phase 3 randomized, double-blind clinical trial in the PARADIGM program, and is expected to enroll participants at approximately 60 clinical sites across the U.S., Europe, and Australia. The first Phase 3 trial, APPROACH, is taking place at approximately 45 clinical sites across the U.S. 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.

Sources

1. Johnson & Johnson. (2025, July 16). Johnson & Johnson reports Q2 2025 results; raises 2025 outlook [Press release]. https://s203.q4cdn.com/636242992/files/doc_financials/2025/q2/2Q25-Earnings-Press-Release-Final-7-15-with-Attachments.pdf

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 participants and add additional clinical sites for the PARADIGM program; the timing of commencement of EMBRACE; the Company's plan to enroll 330 participants at 60 clinical sites across the United States, Europe and Australia for the EMBRACE study; 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. APPROACH and EMBRACE are registered trademarks of Cybin IRL Limited, a subsidiary of Cybin.

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 year ended March 31, 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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