



## Helus Pharma Provides Update on APPROACH Phase 3 Trial Enrollment Progress

June 24, 2026

- APPROACH Phase 3 clinical trial of HLP003 for the adjunctive treatment of major depressive disorder (“MDD”) is progressing as planned and has surpassed 86% enrollment -
- Phase 2 HLP003 data demonstrated long-term efficacy with ~23-point reduction in Montgomery-Asberg Depression Rating Scale (“MADRS”) score compared to baseline at 12 months after two 16 mg doses of HLP003 three weeks apart -
- Previously reported Phase 2 HLP003 results showed response and remission rates of 75% at week 18 and by the 12-month mark, response and remission rates improved to 100% and 71% respectively -
- Previously granted Breakthrough Therapy Designation for HLP003 by the FDA -
- Company remains on track for topline data readout in Q4 2026 -

*This news release constitutes a “designated news release” for the purpose of the Company’s prospectus supplement dated December 30, 2025, to its short form base shelf prospectus dated September 17, 2025, as amended on December 19, 2025.*

NEW YORK and TORONTO, June 24, 2026 (GLOBE NEWSWIRE) -- Helus Pharma™ (Nasdaq: HELP) (Cboe CA: HELP) (the “Company” or “Helus Pharma”), a clinical-stage pharmaceutical company committed to helping minds heal by developing novel serotonergic agonists (“NSAs”), today announced that enrollment in the APPROACH Phase 3 clinical trial of HLP003 for the adjunctive treatment of major depressive disorder (“MDD”) is progressing as planned and has surpassed 86% enrollment.

The APPROACH trial is one of the Company’s Phase 3 studies evaluating HLP003, Helus Pharma’s lead proprietary NSA, which has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration.

“We are pleased with the continued progress of the APPROACH study as we surpass 86% enrollment,” said Eric So, Interim Chief Executive Officer of Helus Pharma. “This milestone underscores the execution of our clinical program and brings us closer to the anticipated topline data readout in the fourth quarter of 2026. We remain focused on advancing HLP003 as a potential transformative treatment option for patients living with MDD.”

The APPROACH study is evaluating the efficacy and safety of HLP003 as an adjunctive treatment in patients with MDD. The trial is part of the Company’s broader Phase 3 PARADIGM program, which also includes the EMBRACE study and the EXTEND long-term extension study, supporting the continued advancement of HLP003 toward potential commercialization.

In previous reported Phase 2 data, HLP003 demonstrated long-term efficacy with ~23-point reduction in Montgomery-Asberg Depression Rating Scale score compared to baseline at 12 months after two 16 mg doses of HLP003 three weeks apart. Phase 2 HLP003 results showed response and remission rates of 75% at week 18 and by the 12-month mark, response and remission rates improved to 100% and 71% respectively.

*This news release does not constitute an offer to sell or the solicitation of an offer to buy securities, nor will there be any sale of the securities, in any jurisdiction in which such offer, solicitation or sale would be unlawful.*

### About Helus Pharma

Helus Pharma™, the commercial operating name of Cybin Inc. is a clinical stage pharmaceutical company committed to helping minds heal by developing proprietary NSAs - novel serotonergic agonists: synthetic molecules designed to activate serotonin pathways that are believed to promote neuroplasticity. The Company’s proprietary NSAs are intended to address the large unmet need for people who suffer from depression, anxiety, and other mental health conditions.

With class leading data, Helus Pharma aims to improve the treatment landscape through the introduction of NSAs that aim to provide durable improvements in mental health. Helus Pharma is currently developing HLP003, a proprietary NSA, in Phase 3 clinical development for the adjunctive treatment of major depressive disorder that has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration and HLP004, also a proprietary NSA in Phase 2 for generalized anxiety disorder. Additionally, Helus Pharma has a portfolio of investigational NSAs.

The Company operates in Canada, the United States, the United Kingdom, and Ireland. For Company updates and to learn more

about Helus Pharma, visit [www.helus.com](http://www.helus.com) or follow the team on X, LinkedIn, YouTube and Instagram. Helus Pharma™ is a trademark of Helus Pharma Corp.

## 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 plan to readout topline data in the fourth quarter of 2026; the Company’s expectation that HLP003 is a transformative treatment option for patients living with MDD; the Company’s progress on and expectations with respect to the APPROACH trial; 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 NSA 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 and nine month periods ended December 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/](http://www.sedarplus.ca/) and the Company’s EDGAR profile at [www.sec.gov/edgar](http://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.

The Company makes no medical, treatment or health benefit claims about the Company’s proposed products. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated claims regarding NSAs or HLP003, HLP004 and other programs of the Company. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of NSAs, HLP003, HLP004 or other programs of the Company can diagnose, treat, cure or prevent any disease or condition. Rigorous scientific research and clinical trials are needed. If Helus Pharma cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company’s performance and operations.

*Neither Cboe Canada, nor the Nasdaq Global Market 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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