Helus Pharma Announces Positive Topline Results from Phase 3 APPROACH Study evaluating HLP003 as Adjunctive Treatment in Major Depressive Disorder

November 16, 2026

HLP003 achieved statistically significant and clinically meaningful results in the primary and key secondary endpoints starting as early as Day 2 and maintained at all time points

-7.6 point placebo-adjusted change from baseline at Week 6 for the primary endpoint on the Montgomery-Asberg Depression Rating Scale ("MADRS") (p< 0.0001)

Durable effect maintained through Week 12 (key secondary endpoint) with a -7.0 point placebo-adjusted change from baseline on the MADRS (p< 0.0001)

Robust and statistically significant response and remission rates starting as early as Day 2 and maintained at all time points

HLP003 was generally well-tolerated

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.

Company to host webcast at 8:00 AM ET today

NEW YORK and TORONTO,, Nov. 16, 2026 (GLOBE NEWSWIRE) -- Helus Pharma Inc. (Nasdaq: HELP) (Cboe CA: HELP) ("Helus Pharma" or the "Company"), a clinical-stage pharmaceutical company committed to improving the treatment landscape in mental health conditions through the development and commercialization of novel serotonergic agonists ("NSAs"), today announced positive topline results from APPROACH, its Phase 3 pivotal study evaluating HLP003 (deuterated psilocin), as an adjunctive treatment for adults with major depressive disorder ("MDD").

HLP003 achieved statistically significant and clinically meaningful results in the primary, key secondary and other secondary endpoints starting as early as Day 2 and these were maintained at all time points.

At the primary endpoint of 6 weeks, the least squares ("LS") mean reduction from baseline in the MADRS total score for HLP003 was 19.5 points versus 11.9 points for placebo (LS mean difference = -7.6 points, p<0.0001, effect size=0.653).

The rapid onset of action with HLP003 was demonstrated with statistically significant LS mean MADRS reductions as early as Day 2 of 16.1 points versus 11.0 points for placebo (LS mean difference = -5.0 points, p=0.0013, effect size=0.438). This effect was durable with an LS mean reduction from baseline in the MADRS total score for HLP003 of 16.9 points versus 9.9 points for placebo (LS mean difference = -7.0 points, p<0.0001, effect size=0.581) at the key secondary endpoint of 12 weeks.

"The large unmet need for patients with major depressive disorder who continue to experience persistent symptoms underscores the importance of new rapid-acting and well-tolerated adjunctive treatment options," said Michael Halstead, Chief Executive Officer of Helus Pharma. "We believe these data demonstrate a therapeutic profile that has the potential to meaningfully improve outcomes for patients and strengthen our momentum as we continue to progress HLP003 toward regulatory approval and potential commercialization."

Other Efficacy Results

HLP003 demonstrated statistically significant and clinically meaningful improvements in response and remission rates as an adjunctive therapy, starting as early as Day 2 and maintained at all time points:

	HLP003 (N=112)	Placebo (N=110)	p-value
Response rate (50% reduction from baseline)			
at Day 2	50.0%	23.6%	0.0002
at Week 6	56.3%	28.2%	<0.0001
at Week 12	45.5%	19.1%	<0.0001

Remission rate (MADRS total score of ≤10)			
at Day 2	39.3%	15.5%	0.0002
at Week 6	50.9%	18.2%	<0.0001
at Week 12	40.2%	15.5%	<0.0001

Additionally, HLP003 demonstrated statistically significant improvements on the Clinical Global Impression Scale compared with placebo starting as early as Day 2 and maintained at all time points.

“The results from the APPROACH study set a new benchmark for what may be achievable with adjunctive treatment in major depressive disorder,” said Roger S. McIntyre, M.D., FRCPC, Professor of Psychiatry and Pharmacology, University of Toronto. “The magnitude of benefit observed in this study is highly compelling and has the potential to redefine expectations among clinicians treating patients who continue to experience depressive symptoms while on an anti-depressant.”

Approximately two-thirds of patients with depression do not achieve remission with first-line antidepressant treatment.[1] For patients who experience an inadequate response, adjunctive therapy is a commonly used treatment strategy. By adding a therapy to an existing antidepressant regimen, clinicians may be able to enhance treatment response while avoiding the need for antidepressant discontinuation, medication washout periods, or the potential withdrawal symptoms associated with switching treatments.

Safety and Tolerability

HLP003 was generally well tolerated in the APPROACH study. Most adverse events were mild to moderate in severity, transient, and primarily limited to the day of dosing. There were three HLP003 treatment-related serious adverse events in the study. No new safety signals were identified.

About APPROACH and the PARADIGM Phase 3 Program

APPROACH is a Phase 3, multicenter, randomized, parallel-group, double blind, placebo-controlled trial of adjunctive treatment with HLP003 of adult participants with MDD. The Phase 3 study evaluated the efficacy and safety of HLP003 compared to placebo. The intent-to-treat population consisted of 222 participants with a DSM-5 confirmed diagnosis of MDD of moderate to severe degree as indicated by a MADRS total score of at least 24 at screening and baseline.

The baseline MADRS total scores of 32.7 for HLP003 and 33.8 for the placebo, reflected participants with moderate to severe depression. Participants continued taking their stable dose of antidepressant medication throughout the study.

APPROACH is the first of the three studies in the PARADIGM Phase 3 program, that also includes EMBRACE, the second pivotal study which is currently ongoing and the EXTEND study. The Company expects to report topline results from the EMBRACE trial in 4Q 2027. [2,3]

EXTEND is the ongoing long-term extension study which will provide additional data on long-term safety, durability of effect, and the potential role of redosing. Participants from APPROACH and EMBRACE may roll into EXTEND.

Conference Call and Webcast

Helus Pharma will host a conference call and webcast today at 8:00 am ET to discuss results. To access the webcast, please visit the Events & Presentation page of Helus Pharma’s website. The archived webcast will be available on the Company’s website on the Events & Presentations page following the presentation.

About Helus Pharma

Helus Pharma is a clinical stage pharmaceutical company committed to improving the treatment landscape in mental health through the development of NSAs, 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.

Helus Pharma is currently developing HLP003, a proprietary NSA, in Phase 3 clinical development for the potential 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 an extensive research 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 or follow the team on X, LinkedIn, YouTube and Instagram. Helus Pharma™ is a trademark of Helus Pharma Corp.

Notes

1. Pigott HE, et al., BMJ Open. 2023;13(7):e063095.

2. There is no assurance that this timeline will be met or that the program will advance clinical trials, at all. Drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development and recruitment of patients for participation in clinical trials are dependent on various factors and are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, eligibility and exclusion criteria for the trial, design of the clinical trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, the number, availability, location and accessibility of clinical trial sites, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.

3. Anticipated timelines regarding the initiation, advancement and results of clinical trials are based on reasonable assumptions informed by current knowledge and information available to the Company. See "Forward-Looking Statements".

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 claim that the data demonstrate a therapeutic profile that has the potential to meaningfully improve outcomes for patients; expectations to report topline results from the EMBRACE trial in 4Q 2027; the potential regulatory approval and commercialization of HLP003; the APPROACH study's potential to set higher expectations among clinicians treating patients who continue to experience depressive symptoms while on an anti-depressant; expectations of the EXTEND study, including the roll-in enrollment of participants from EMBRACE and APPROACH; HLP003 as a potential adjunctive treatment for MDD; 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; and the timing of any of the foregoing.

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; the results of the Company's clinical trials; the Company's ability to pursue and obtain regulatory approval for its product candidates; the Company's ability to enroll and retain participants in its clinical trials; the Company's need for additional financing; the Company's dependence on key personnel, including in connection with recent changes in management; the regulation of controlled substances; 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 six months ended September 30, 2026, and the Company's annual information form for the year ended March 31, 2026, 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.

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. 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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