



Nature Medicine Publishes Helus Pharma's Randomized, Placebo-Controlled Phase 2a Trial of SPL026 in Major Depressive Disorder

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- *Randomized, placebo-controlled Phase 2a study of SPL026 met its primary endpoint demonstrating a clinically significant reduction in depressive symptoms as measured by MADRS score (mean difference: -7.35) versus placebo at two weeks*
- *Antidepressant treatment effects observed within one week and sustained for up to three months*
- *Findings reinforce the therapeutic potential of short-acting serotonergic agonists and inform Helus Pharma's HLP004 development program, with Phase 2 topline data in generalized anxiety disorder ("GAD") expected in Q1 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.

BOSTON and TORONTO, Feb. 17, 2026 (GLOBE NEWSWIRE) -- Helus Pharma™ (Nasdaq: HELP) (Cboe CA: HELP), a clinical-stage pharmaceutical company developing novel serotonergic agonists ("NSAs") for serious mental health conditions, today announced the publication¹ in *Nature Medicine* of results from a Phase 2a randomized, placebo-controlled clinical trial evaluating SPL026, in participants with moderate-to-severe major depressive disorder ("MDD").

The study met its primary endpoint demonstrating statistically significant and clinically meaningful reductions in depressive symptoms at two weeks, as measured by the Montgomery-Åsberg Depression Rating Scale ("MADRS") in participants treated with SPL026 compared with placebo. Reductions in depressive symptoms were observed as early as one week following dosing and were sustained at three months, with effects lasting up to six months in some participants. The treatment was generally well tolerated, with no treatment-related serious adverse events reported.

"We have shown that a single dose of SPL026 is safe, effective and durable, with treatment effects comparable to other promising interventional treatments often requiring much longer treatment sessions." Dr David Erritzoe, from Imperial's Department of Brain Sciences, and lead investigator of the trial continued, "Although such early trial results should always be interpreted with some caution, these data show the promise of DMT as a potentially more cost-effective treatment for clinical depression than related serotonergic agonists with longer psychoactive action due to the shorter dosing sessions."

This phase 2a study evaluated the efficacy and safety of SPL026. Participants receiving a single 21.5 mg dose of SPL026 (n=17) demonstrated a significant reduction in MADRS score compared to placebo (n=17) at two weeks meeting the primary endpoint (mean difference: -7.35; 95%CI, -13.62 to -1.08; p=0.023). The treatment effect of SPL026 was evident at one week (mean difference: -10.75; 95%CI, -16.95 to -4.55; p=0.002). Response rates (≥50% MADRS reduction) at Week 2 were 35% for SPL026 vs. 12% for placebo, with remission rates (MADRS ≤10) at 29% vs. 12%. During the open-label portion of the study, the treatment effect was maintained for up to three months.

"This publication represents an important validation of short-acting serotonergic agonists as a clinically meaningful approach in mental health treatments," said Michael Cola, Chief Executive Officer of Helus Pharma. "The findings provide clinical proof-of-concept for short-acting serotonergic modulation and further support our conviction that our novel serotonergic agonist molecules, such as HLP004, can potentially deliver meaningful outcomes with greater consistency and commercial feasibility. We look forward to reporting topline data from our Phase 2 study of HLP004 in generalized anxiety disorder later this quarter."

Although Helus Pharma is not advancing intravenous SPL026 in its current form, the mechanistic and clinical insights generated from this trial continue to inform the Company's HLP004 development program. Helus is currently advancing HLP004, a proprietary NSA, that is designed to optimize pharmacology, consistency, and scalability for GAD, of which SPL026 is a nondeuterated analog.

¹*Erritzoe et. al., A short-acting psychedelic intervention for major depressive disorder: randomized placebo-controlled IIa trial of intravenous dimethyltryptamine (DMT), Nature Medicine. DOI 10.1038/s41591-025-04154-z*

About the Study

The study was conducted at Hammersmith Medicines Research Ltd (London), MAC Clinical Research (Liverpool), and Imperial College London. This study was conducted by Helus Pharma Corp., a wholly owned subsidiary of Helus Pharma and the successor entity to Small Pharma Inc. The study was a phase 2a randomized placebo-controlled trial evaluating the safety and

efficacy of SPL026, in adults with moderate-to-severe major depressive disorder. The trial enrolled 34 participants (mean age 32.8 years, 29.4% female, predominantly white) who had experienced depression for an average of 10.5 years. Participants were randomized in a double-blind manner to receive either a single 21.5 mg intravenous infusion of SPL026 over 10 minutes or placebo, combined with supportive psychotherapy sessions focused on preparation, integration, and emotional processing.

In the blinded Stage 1, the primary endpoint was the change in MADRS scores from baseline to Week 2. Stage 2 was an open-label extension where all participants could receive a second SPL026 dose two weeks later; antidepressant effects persisted up to three months post-first dose.

About Helus Pharma

Helus Pharma™, the commercial operating name of Cybin Inc. (the “Company” or “Helus Pharma”) is a clinical stage pharmaceutical company committed to helping minds heal by developing proprietary NSAs: synthetic molecules designed to activate serotonin pathways that are believed to promote neuroplasticity. The Company’s proprietary NSAs are intended to potentially 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 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 Cybin 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 anticipated topline data readout from the Phase 2 study evaluating HLP004 in GAD in Q1 2026; the promise of SPL026 as a potentially more cost-effective treatment for clinical depression; the ability of the Company’s NSAs to address the large unmet need for people who suffer from depression, anxiety, and other mental health conditions; the Company’s notion that novel serotonergic agonist molecules, such as HLP004, can potentially deliver meaningful outcomes with greater consistency and commercial feasibility; 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 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. 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.

Investor Contact:

Josh Barer
astr partners
Managing Director
(908) 578-6478
josh.barer@astrpartners.com

George Tziras
Chief Business Officer
Helus Pharma
1-866-292-4601
irteam@helus.com – or – media@helus.com

Media Contact:

Johnny Tokarczyk
RXMD
Public Relations Director
(914) 772-7562
jtokarczyk@rxmedyn.com