Amylyx Pharmaceuticals Presents Results from Phase 3 LUCIDITY Clinical Trial of Avexitide in Post-Bariatric Hypoglycemia at ObesityWeek® 2026 Annual Meeting

November 14, 2026

- *LUCIDITY met its prespecified primary endpoint; avexitide reduced the composite Level 2/3 hypoglycemic event rate by 55% compared to placebo (p=0.000003)*
- *Avexitide showed consistent, highly statistically significant reductions across all prespecified, multiplicity-controlled secondary event-rate endpoints vs. placebo*
- *Avexitide was generally well-tolerated with a favorable safety profile; adverse events during the double-blind treatment period were generally mild to moderate in severity*
- *Company to host an in-person and webcast investor KOL event tomorrow, November 15, at 11:45 AM ET*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 14, 2026-- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") will present the results from the 16-week double-blind treatment period of the Phase 3 LUCIDITY clinical trial of avexitide, an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist, in participants with post-bariatric hypoglycemia (PBH) following Roux-en-Y gastric bypass (RYGB) surgery, in a late-breaking oral presentation on November 15th at the ObesityWeek® 2026 Annual Meeting.

"The presentation of our Phase 3 LUCIDITY results represents a pivotal milestone in our work to address the longstanding treatment gap for people living with PBH. The results shared today reinforce the consistency and strength of the data, with avexitide demonstrating highly statistically significant and clinically meaningful reductions in hypoglycemic events across all prespecified endpoints," said Camille L. Bedrosian, MD, Chief Medical Officer at Amylyx. "These positive data, together with positive results from five prior trials of avexitide in PBH, support the potential for avexitide to change practice for this debilitating condition."

LUCIDITY met its prespecified primary endpoint, demonstrating a 55% reduction in the composite rate of self-monitoring of blood glucose (SMBG)-confirmed Level 2 and blinded Event Adjudication Committee (EAC)-adjudicated Level 3 hypoglycemic events compared with placebo (Least squares mean event rate of 0.55 events per week in avexitide arm compared to 1.24 events per week in placebo arm, p=0.0000034). LUCIDITY also met all prespecified, multiplicity-controlled secondary event-rate endpoints, reducing SMBG-confirmed Level 2 hypoglycemic events by 63% (p=0.0000032), EAC-adjudicated Level 3 hypoglycemic events by 47% (p=0.0016), and continuous glucose monitoring (CGM)-detected Level 2 hypoglycemic events by 42% (p=0.00016) compared with placebo. In a secondary analysis that evaluated change from baseline within each arm, events decreased by 72.9% in the avexitide arm and by 37.8% in the placebo arm (p=0.000034 for the between-arm difference).

Avexitide was generally well tolerated, with a safety profile consistent with that observed across prior PBH clinical trials. Treatment-emergent adverse events were primarily gastrointestinal and injection-site related and were generally mild to moderate in intensity. There were no deaths and no treatment-related serious adverse events. No clinically meaningful changes in body weight or fasting plasma glucose were observed during the 16-week double-blind treatment period.

"PBH is a chronic metabolic condition characterized by recurrent hypoglycemia. Each hypoglycemic event carries the potential for serious acute consequences and the cumulative burden of living with recurrent and unpredictable events can significantly affect daily functioning, independence, health and quality of life," said Marilyn Tan, MD, FACE, FACP, Principal Investigator of the LUCIDITY clinical trial and Clinical Professor at the Stanford School of Medicine. "The debilitating nature of this condition is clear when you look at the participants of LUCIDITY. At baseline, the majority of participants entered the study experiencing daily hypoglycemia symptoms, with many reporting a history of loss of consciousness and hypoglycemia-related hospitalizations. This substantial disease burden makes the consistent reductions in hypoglycemic events seen with avexitide compelling."

LUCIDITY is a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial that enrolled 78 adults with PBH following RYBG surgery. After a 3-week run-in, participants were randomized 3:2 to avexitide 90mg subcutaneously once daily or placebo. Participants received standard-of-care dietary management for PBH throughout the run-in and 16-week double-blind treatment period. More than 90% of participants completed the double-blind treatment period, including 45/47 participants randomized to avexitide and 28/31 randomized to placebo. All eligible participants entered the 32-week open-label extension period. Baseline demographic and disease characteristics were generally balanced between groups. Participants in LUCIDITY had substantial disease burden at baseline: 68% reported daily hypoglycemic symptoms, 47% had a history of loss of consciousness, and 28% had a history of hypoglycemia-related hospitalizations.

"We're profoundly grateful to everyone who made LUCIDITY possible — from the people living with PBH who participated in our trial, to their families and care partners, as well as the investigators who share our commitment to improve outcomes for this serious condition," said Justin Klee and Joshua Cohen, Co-CEOs of Amylyx. "These results bring us meaningfully closer to what could be the first approved treatment for a community that has been waiting far too long for one. We're moving with urgency toward an NDA submission by year end and continue to prepare for a potential commercial launch of avexitide in 2027, if approved."

The FDA previously granted avexitide Breakthrough Therapy Designation for PBH. LUCIDITY's 32-week open label extension period and the avexitide Expanded Access Program for eligible adults with PBH following RYGB surgery remain ongoing.

The ObesityWeek® 2026 Annual Meeting presentations can be accessed on the "Presentations" tab of the Amylyx website.

Webcast Information
Amylyx will host an investor key opinion leader (KOL) event tomorrow, November 15, at 11:45 AM ET both in-person and virtually to discuss the Phase 3 LUCIDITY results. A live webcast of the presentation and Q&A portion of the event can be accessed under "Events and Presentations" in the Investor section of the Company's website, https://investors.amylyx.com/events-presentations. The webcast will be archived and available for replay for 90 days following the event.

About Avexitide
Avexitide is an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist that has been evaluated in six clinical trials for post-bariatric hypoglycemia (PBH) and has also been studied in congenital hyperinsulinism (HI). The U.S. Food and Drug Administration (FDA) has granted avexitide Breakthrough Therapy Designation for both indications, Rare Pediatric Disease Designation in congenital HI, and Orphan Drug Designation for the treatment of hyperinsulinemic hypoglycemia (which includes PBH and congenital HI). In PBH, an exaggerated GLP-1 response leads to excessive insulin secretion, resulting in recurrent hypoglycemic events. Avexitide is a competitive GLP-1 receptor antagonist designed to bind to the GLP-1 receptor on pancreatic islet beta cells and inhibit the exaggerated GLP-1-driven insulin response characteristic of PBH, reducing inappropriate insulin secretion and stabilizing blood glucose levels. In two Phase 2 and the Phase 3 LUCIDITY clinical trials in PBH, avexitide demonstrated highly statistically significant reductions in hypoglycemic events.

About Post-Bariatric Hypoglycemia (PBH)
PBH is a chronic metabolic condition that is estimated to affect approximately 8% of people in the U.S. who have undergone the two most common types of bariatric surgery, sleeve gastrectomy and Roux-en-Y gastric bypass (approximately 160,000 people in the U.S.). PBH is thought to be driven by an exaggerated glucagon-like peptide-1 (GLP-1) response, primarily in response to food intake, leading to persistent, recurrent, and often debilitating rapid drops in blood glucose, known as hypoglycemia. The American Diabetes Association (ADA) recognizes hypoglycemia as a potential medical emergency because low blood glucose levels can compromise the body's ability to maintain essential physiologic processes. In addition, hypoglycemia in the context of PBH may manifest as neuroglycopenia – an inadequate supply of glucose to the brain – which can cause confusion, cognitive dysfunction, loss of consciousness, and seizures. PBH can be associated with substantial disability, compromising safety, disrupting independent living, and affecting nutritional status and overall quality of life. Despite the substantial burden, there are currently no FDA-approved therapies for PBH.

About the LUCIDITY Trial
LUCIDITY (NCT06747468) is a 78-participant, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of avexitide in participants with PBH following RYGB surgery. The Phase 3 trial was conducted at 21 sites in the U.S. Participants were randomized 3:2 to receive either 90 mg of avexitide subcutaneously once daily or placebo. The trial includes an up to six-week screening period, including a three-week run-in period, a 16-week double-blind treatment period, and a 32-week open-label extension (OLE) period. The primary efficacy objective of LUCIDITY was to evaluate the FDA-agreed upon primary outcome of reduction in the composite of Level 2 and Level 3 hypoglycemic events through Week 16. Safety and tolerability were also evaluated.

About Amylyx Pharmaceuticals
At Amylyx, our purpose is guided by an unwavering commitment to the communities we serve as we discover and advance novel therapies for debilitating diseases and conditions with high, often underrecognized, unmet medical needs. Our approach is not limited to any single condition, disease, or modality and is rooted in understanding the underlying biological drivers to advance meaningful progress in how diseases and conditions are understood and treated. We are currently focused on endocrine conditions and neurodegenerative diseases where we believe we can make the greatest impact. For more information, visit amylyx.com and follow us on LinkedIn and X. For investors, please visit investors.amylyx.com.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, Amylyx's expectations regarding: the therapeutic potential and safety of avexitide as a treatment for PBH; expectations regarding the timing for NDA submission with the U.S. Food and Drug Administration; the potential benefits of regulatory designations held with the FDA; and expectations regarding timing for potential commercialization of avexitide, if approved. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the

forward-looking statements include: the success, cost, and timing of Amylyx's program development activities; Amylyx's ability to execute on its regulatory development plans and expectations regarding the timing of results from its planned data announcements and initiation of clinical studies; the risk that early-stage results may not reflect later-stage results; Amylyx's ability to fund operations, and the impact that global macroeconomic uncertainty, geopolitical instability, and public health events will have on Amylyx's operations, as well as the risks and uncertainties set forth in Amylyx's United States Securities and Exchange Commission (SEC) filings, including Amylyx's Annual Report on Form 10-K for the year ended December 31, 2025, and subsequent filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Amylyx undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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