Amylyx Pharmaceuticals Announces Completion of Enrollment in Pivotal Phase 3 LUCIDITY Clinical Trial of Avexitide in Post-Bariatric Hypoglycemia

March 24, 2026

- *Last participant has been randomized and dosed in the LUCIDITY trial of avexitide; LUCIDITY enrolled a total of 78 participants*
- *Topline data readout on track; anticipated in Q3 2026*
- *LUCIDITY is evaluating the FDA-agreed-upon primary outcome of reduction in the composite of Level 2 and Level 3 hypoglycemic events through Week 16*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 24, 2026-- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today announced that the last participant has been randomized and dosed in the pivotal Phase 3 LUCIDITY clinical trial of avexitide, an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist with U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation in post-bariatric hypoglycemia (PBH). LUCIDITY is a 16-week, multicenter, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of avexitide in adults with PBH following Roux-en-Y gastric bypass (RYGB) surgery. Participants who complete the 16-week double-blind period are eligible to enter a 32-week open-label extension period. The trial has enrolled 78 participants, with topline data readout anticipated in Q3 2026. If approved, commercial launch of avexitide is anticipated in 2027.

"We are pleased to have completed enrollment in our pivotal Phase 3 LUCIDITY trial, and we extend our gratitude to the LUCIDITY trial sites and participants for their continued contributions to the trial," said Camille L. Bedrosian, MD, Chief Medical Officer at Amylyx. "We remain encouraged by the statistically significant data generated in five previous Phase 1 and Phase 2 clinical trials of avexitide in PBH, including statistically significant reductions in hypoglycemic events. Early NDA-readiness preparations are currently underway, and we look forward to topline data expected in Q3 2026."

"Today, living with PBH means living with constant and unpredictable hypoglycemic events, which studies have shown are driven by an exaggerated GLP-1 response. These events can lead to severe medical consequences, such as seizures, loss of consciousness, emergency department visits, hospitalization, and long-term impacts, including cognitive dysfunction. The significant burden of this chronic metabolic condition can strip away independence, forcing many of my patients to withdraw from their work and social lives," said Marilyn Tan, MD, FACE, Principal Investigator of the LUCIDITY clinical trial. "Preventing even a single event could meaningfully improve someone's quality of life and there is an urgent need for medicine to treat this devastating condition." Dr. Tan is also a Clinical Professor of Medicine at the Stanford School of Medicine.

LUCIDITY is evaluating the FDA-agreed-upon primary outcome of reduction in the composite of Level 2 and Level 3 hypoglycemic events through Week 16. LUCIDITY was informed by data from five PBH clinical trials of avexitide showing consistent effects, most notably statistically significant reductions in Level 2 and Level 3 hypoglycemic events. Avexitide was generally well-tolerated, with a favorable safety profile replicated across clinical trials.

About Avexitide

Avexitide is an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist that has been evaluated in five Phase 1 and Phase 2 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 PBH clinical trials, 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 is being 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 an open-label extension (OLE) period with a duration of 32 weeks. The primary efficacy objective of LUCIDITY is 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 will also be evaluated.

About Amylyx Pharmaceuticals

At Amylyx, our mission is to usher in a new era of treating diseases with high unmet needs. Where others see challenges, we see opportunities that we pursue with urgency, rigorous science, and unwavering commitment to the communities we serve. We are currently focused on four investigational therapies across several endocrine conditions and neurodegenerative diseases in which we believe 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 potential of avexitide as a treatment for PBH; expectations regarding the timing for topline data readout of the Phase 3 LUCIDITY trial of avexitide; and expectations regarding timing for potential commercialization of avexitide. 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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