Amylyx Pharmaceuticals Appoints Dan Monahan as Chief Commercial Officer

January 6, 2025

- Dan Monahan will lead the commercialization strategy across Amylyx' product portfolio, beginning with avexitide, an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist for the treatment of post-bariatric hypoglycemia (PBH)

- Mr. Monahan has more than 20 years of commercial leadership experience, including launching industry-leading franchises at Otsuka, Novartis, and Sanofi

- Strong commercial and medical team in place for potential first-to-market launch in PBH and advancement of late-stage pipeline with the goal to bring new potential treatment options to communities with high unmet need

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 6, 2025-- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today announced the appointment of Dan Monahan as Chief Commercial Officer. Mr. Monahan will also join the Company's Leadership Team. Mr. Monahan joined Amylyx in January 2024, bringing more than 20 years of commercial leadership experience in the biopharmaceutical industry overseeing sales, marketing, and market access for multiple product lines.

"We are excited to announce the appointment of Dan Monahan to Chief Commercial Officer as Amylyx prepares for the first participant dosed in the Phase 3 LUCIDITY clinical trial of avexitide for the treatment of post-bariatric hypoglycemia planned in the first quarter of 2025. Dan has a strong track record of launching medicines and excels in building and leading high-performing teams that have brought new medicines to communities with high unmet needs," said Joshua Cohen and Justin Klee, Co-CEOs of Amylyx. "Since joining Amylyx earlier this year, Mr. Monahan has demonstrated invaluable leadership as we work towards ensuring launch readiness for the avexitide program ahead of Phase 3 data expected in 2026 and potential future launches. We are confident that the addition of Mr. Monahan to our leadership team will play a crucial role in delivering a meaningful impact to the PBH community as we continue to move forward in our goal for avexitide to be the first therapy approved for people living with PBH."

Throughout his career, Mr. Monahan has remained deeply committed to launching therapies that address high unmet medical needs, bringing critical treatments to those who need them most. Prior to joining Amylyx, Mr. Monahan served as Vice President, Head of CNS Marketing and Portfolio Strategy at Otsuka Pharmaceuticals, where he led the U.S. commercialization efforts for the company's CNS franchise, including REXULTI ® and ABILIFY MAINTENA®, which played a critical role in treating serious mental health conditions. Before joining Otsuka, Mr. Monahan held senior leadership roles at Novartis. He led the commercial execution of the company's flagship blockbuster dermatology brand, COSENTYX ®, for patients with autoimmune conditions. Prior to Novartis, Mr. Monahan spent 14 years at Sanofi in positions of increasing leadership responsibility across sales, marketing and market access. He received an MBA from Seton Hall University, and is a graduate of the United States Military Academy at West Point. Dan served as a Field Artillery Officer in the U.S. Army.

"I look forward to continuing to collaborate with the team on advancing novel therapies from development through commercialization, with our first focus on avexitide for the potential treatment of post-bariatric hypoglycemia," said Dan Monahan, Chief Commercial Officer of Amylyx. "Since joining Amylyx, I have seen first-hand both the resilience of those with post-bariatric hypoglycemia and the significant quality of life impacts that this debilitating condition can have. I am deeply motivated by the opportunity to support people living with PBH and potentially addressing the critical unmet need for a treatment option."

In this role, Mr. Monahan will lead the Company's commercialization efforts, particularly as Amylyx prepares for the potential approval of avexitide, an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist for the treatment of post-bariatric hypoglycemia (PBH). Amylyx plans to initiate LUCIDITY, a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial designed to evaluate the efficacy and safety of avexitide in participants with PBH in the first quarter of 2025.

About Avexitide

Avexitide is an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist that has been evaluated in five 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). Avexitide is designed to bind to the GLP-1 receptor on pancreatic islet beta cells and inhibit the effect of GLP-1 to mitigate hypoglycemia by decreasing insulin secretion and stabilizing blood glucose levels. In PBH, excessive GLP-1 can lead to the hypersecretion of insulin and subsequent debilitating hypoglycemic events. In two Phase 2 PBH trials, avexitide demonstrated highly statistically significant reductions in hypoglycemic events. These events can lead to autonomic and neuroglycopenic symptoms that can have a devastating impact on daily living.

About the LUCIDITY Trial

LUCIDITY (NCT06747468) is a 75-participant, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of avexitide in participants with PBH. The Phase 3 trial will be conducted at approximately 20 sites in the U.S. Participants will be randomized 3:2 to receive either 90 mg of avexitide subcutaneously once daily or placebo. The trial will include a three-week run-in period and a 16-week double-blind treatment period. Participants who complete the double-blind period of the planned study will be eligible to enter an open-label extension (OLE) period with a duration of 32 weeks. The primary efficacy objective of LUCIDITY will 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 Post-Bariatric Hypoglycemia (PBH)

Symptomatic post-bariatric hypoglycemia (PBH) is a condition that affects approximately 8% of people who have undergone bariatric surgery, or approximately 160,000 people, in the U.S. PBH is thought to be caused by an excessive glucagon-like peptide-1 (GLP-1) response leading to hypoglycemia and impaired quality of life. PBH can cause debilitating hypoglycemic events associated with inadequate supply of glucose to the brain, known as neuroglycopenia. Clinical manifestations can include impaired cognition, loss of consciousness, and seizures. PBH is also associated with a high degree of disability that can result in major disruptions to independent living. There are no approved therapies for PBH.

About Amylyx Pharmaceuticals

Amylyx is committed to the discovery and development of new treatment options for communities with high unmet needs, including people living with serious and fatal neurodegenerative diseases and endocrine conditions. Since its founding, Amylyx has been guided by science to address unanswered questions, keeping communities at the heart and center of all decisions. Amylyx is headquartered in Cambridge, Massachusetts. 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 and related comments in our earnings conference call 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, the potential of avexitide as a treatment for PBH; and expectations regarding the timing of initiation of a Phase 3 trial of avexitide in PBH. Any forward-looking statements in this press release and related comments in the Company's earnings conference call 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’ program development activities; Amylyx’ 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’ ability to fund operations, and the impact that global macroeconomic uncertainty, geopolitical instability, and public health events will have on Amylyx’ operations, as well as the risks and uncertainties set forth in Amylyx’ United States Securities and Exchange Commission (SEC) filings, including Amylyx’ Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent filings with the SEC. All forward-looking statements contained in this press release and related comments in our earnings conference call 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.

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