



Amylyx Pharmaceuticals Announces Nomination of AMX0318 as a Novel, Long-Acting GLP-1 Receptor Antagonist Development Candidate, Identified in Collaboration with Gubra

- *AMX0318 selected as development candidate after meeting key criteria, demonstrating a robust chemical stability profile, strong in vitro potency, evidence of in vivo efficacy and tolerability, high solubility, and a favorable pharmacokinetic profile consistent with a long-acting peptide*
- *IND-enabling studies expected to initiate in 2026 with an IND targeted for 2027, pending successful completion of IND-enabling studies*

CAMBRIDGE, Mass. January 8, 2026 – [Amylyx Pharmaceuticals, Inc.](#) (NASDAQ: AMLX) ("Amylyx" or the "Company") today announced the selection of AMX0318, a long-acting glucagon-like peptide-1 (GLP-1) receptor antagonist, as a development candidate for post-bariatric hypoglycemia (PBH) and other rare diseases. AMX0318 was identified through a research collaboration with Gubra A/S ("Gubra"), a company specializing in peptide-based drug discovery and preclinical contract research services.

"We are very pleased to nominate AMX0318 as a development candidate and were highly impressed by Gubra's proprietary and innovative process, which identified a peptide that surpassed our research target profile for a long-acting GLP-1 receptor antagonist. AMX0318 has thus far shown robust preclinical and chemical properties, including a pharmacokinetic profile that may support long-acting administration," said Camille L. Bedrosian, MD, Chief Medical Officer at Amylyx. "We are excited about the opportunity to develop additional therapeutic possibilities for people who may benefit from inhibiting GLP-1 receptor activity, including people with PBH and other rare diseases. The GLP-1 receptor is a well-characterized biological target and one of the key regulators of glucose-insulin homeostasis."

Dr. Bedrosian continued, "We have strong conviction that inhibiting GLP-1 receptor activity represents an important therapeutic approach given the statistically significant data that avexitide, our investigational, first-in-class GLP-1 receptor antagonist, has generated to date. We continue to expect completion of recruitment in our pivotal Phase 3 LUCIDITY trial of avexitide in Q1 2026, with topline data expected in Q3 2026."

AMX0318 has completed extensive preclinical evaluation, including stability, solubility, potency, *in vivo* pharmacokinetics and pharmacodynamics, and *in vivo* tolerability studies. Amylyx expects the program to advance into investigational new drug (IND)-enabling studies later this year, with an IND targeted for 2027, pending successful completion of IND-enabling studies.

"We are pleased to see AMX0318 advance as a development candidate, a milestone that reflects



both the strong collaboration between the Gubra and Amylyx teams and the capabilities of Gubra's proprietary peptide drug discovery platform," said Louise S. Dalbøge, Chief Science Officer at Gubra. "Our AI-driven streaMLine platform enables multi-parameter optimization of peptide candidates, and we are excited to see this applied successfully to AMX0318 in close collaboration with Amylyx."

Under the terms of the research collaboration, Gubra is eligible to receive more than \$50 million in success-based development and commercialization milestones plus mid-single digit royalties on worldwide net sales. The selection and handover of the development candidate will provide milestone payments of \$4 million to Gubra.

About Gubra

Gubra, founded in 2008 in Denmark and listed on NASDAQ Copenhagen, is a disease-agnostic techbio company specialized in peptide-based drug discovery and preclinical contract research services. Gubra's activities are focused on the early stages of drug development and are organized in two main business units – Biotech (D&P) and CRO services. The two business areas are highly synergistic and create a unique entity capable of generating a steady cash flow from the CRO business while investing in high-impact biotech R&D projects with significant value inflection potential through partnerships. Gubra has around 300 employees and had revenue of DKK 2.6 billion (around EUR 350 million) in the first 9 months of 2025. See www.gubra.dk for more information.

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 neurodegenerative and endocrine diseases in which we believe they 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.

Amylyx 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' expectations regarding: the therapeutic potential for AMX0318, the expected timeline for the IND-enabling studies and IND submission for AMX0318, the payments and royalties to be received by Gubra, and the expected timeline for certain development, regulatory, and commercial milestones. 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' 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, 2024 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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Attachments

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