Amylyx Pharmaceuticals Stock Trading Halted Today

September 7, 2022

- *Second FDA Advisory Committee Meeting to Discuss NDA for AMX0035 for the Treatment of ALS*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 7, 2022-- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today announced that Nasdaq has halted trading of the Company's common stock.

The second meeting of the U.S. Food and Drug Administration's (FDA) Peripheral and Central Nervous System Drugs Advisory Committee (PCNSDAC) is occurring today to review the New Drug Application (NDA) for AMX0035 (sodium phenylbutyrate and taurursodiol [also known as ursodoxicoltaurine]) for the treatment of amyotrophic lateral sclerosis (ALS).

The Advisory Committee meeting is scheduled for 12:00 p.m. ET. The briefing materials can be found on the FDA website here. The Company is not responsible for the content of, nor the statements made in, the briefing materials that were prepared by the FDA.

The PCNSDAC previously met on March 30, 2022 to discuss the NDA for AMX0035 for the treatment of ALS. The Prescription Drug User Fee Act (PDUFA) target action date for the NDA is September 29, 2022.

About Amylyx Pharmaceuticals

Amylyx Pharmaceuticals, Inc. is committed to supporting and creating more moments for the neurodegenerative community through the discovery and development of innovative new treatments. Amylyx is headquartered in Cambridge, Massachusetts and has operations in Canada and EMEA. For more information, visit amylyx.com and follow us on LinkedIn and Twitter. 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, statements regarding beliefs about the potential regulatory approval of AMX0035, among others. Any forward-looking statements in this statement 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 strategy, regulatory developments, expectations regarding the timing of regulatory review of AMX0035 and the inherent unpredictability of the regulatory review process, Amylyx' ability to fund operations, and the impact that the ongoing COVID-19 pandemic will have on Amylyx' operations, as well as those 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, 2021, 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.

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