Amylyx Pharmaceuticals Announces Posting of Briefing Documents for FDA Advisory Committee Meeting on AMX0035

March 28, 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 28, 2022-- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) (“Amylyx” or the “Company”) today announced that the U.S. Food and Drug Administration (FDA) posted briefing documents for the March 30, 2022 Peripheral and Central Nervous System Drugs Advisory Committee (PCNSDAC) meeting to review the Company’s New Drug Application (NDA) for AMX0035 (sodium phenylbutyrate [PB] and taurursodiol [TURSO; also known as ursodoxicoltaurine]) for the treatment of amyotrophic lateral sclerosis (ALS).

The Advisory Committee meeting is scheduled for 10 a.m. ET on Wednesday, March 30, 2022. The briefing materials and webcast information can be accessed 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 Prescription Drug User Fee Act (PDUFA) target action date for the AMX0035 NDA is June 29, 2022.

About AMX0035

AMX0035 is a proprietary oral fixed-dose combination of two small molecules: sodium phenylbutyrate (PB), which is a small molecular chaperone designed to reduce the unfolded protein response (UPR), preventing cell death resulting from the UPR, and taurursodiol (TURSO; also known as ursodoxicoltaurine), which is a Bax inhibitor designed to reduce cell death through apoptosis. PB and TURSO were combined in a fixed-dose formulation in an effort to reduce neuronal death and dysfunction. AMX0035 is designed to target the endoplasmic reticulum and mitochondrial-dependent neuronal degeneration pathways in ALS and other neurodegenerative diseases.

About Amylyx Pharmaceuticals

Amylyx Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company working on developing a novel therapeutic for amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases. For more information, visit www.amylyx.com and follow us on LinkedIn and Twitter. For investors, please visit www.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 the potential approval of AMX0035 for the treatment of ALS; and the potential of AMX0035 as a treatment for ALS. 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: regulatory developments and expectations regarding the timing of FDA review of AMX0035 for the treatment of ALS, and the impact that the ongoing COVID-19 pandemic will have on FDA review timelines, as well as those risks and uncertainties set forth in Amylyx’ United States Securities and Exchange Commission filings. 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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