Amylyx Pharmaceuticals Stock Trading Halted Today

March 30, 2022

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

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 30, 2022-- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) today announced that Nasdaq has halted trading of the company's common stock.

The U.S. Food and Drug Administration's (FDA) Peripheral and Central Nervous System Drugs Advisory Committee (PCNSDAC) is meeting today to review the 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 10:00 a.m. ET. The briefing materials can be found on the FDA website here.

The Prescription Drug User Fee Act (PDUFA) target action date for the AMX0035 NDA is June 29, 2022.

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; the potential of AMX0035 as a treatment for ALS; and expectations regarding our longer-term strategy. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220330005162/en/

Media
Becky Gohsler
Finn Partners
(646) 307-6307
Becky.Gohsler@finnpartners.com

Investors
Lindsey Allen
Amylyx Pharmaceuticals, Inc.
(857) 320-6244
Investors@amylyx.com

Source: Amylyx Pharmaceuticals, Inc.