Amylyx Pharmaceuticals Announces ALBRIOZA™ is Now Available in Canada for the Treatment of ALS

July 29, 2022

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 29, 2022-- Amylyx Pharmaceuticals, Inc. (NASDAQ: AMLX) ("Amylyx" or the "Company") today announced that ALBRIOZA™ (sodium phenylbutyrate and ursodoxicoltaurine) is now commercially available in Canada for people living with amyotrophic lateral sclerosis (ALS). ALBRIOZA (also known as AMX0035) is an oral fixed-dose combination therapy that may reduce neuronal cell death as a stand-alone therapy or when added to existing treatments. In a clinical trial, ALBRIOZA significantly slowed disease progression and loss of functional decline in people living with ALS.

"We have remained steadfast in our commitment to ensure ALBRIOZA would be available in Canada as quickly as possible following Health Canada's decision to approve ALBRIOZA, with conditions, in June," said Margaret Olinger, Chief Commercial Officer at Amylyx. "We are pleased that starting this week, we are ready to fill prescriptions for ALBRIOZA."

Amylyx filed reimbursement submissions to the Canadian Agency for Drugs and Technologies (CADTH) and Institut national d'excellence en santé et en services sociaux (INESSS) in Quebec as part of an aligned Health Technology Assessments (HTA) review with Health Canada in parallel with the regulatory process to reduce the timelines required for patient access. The Company is continuing to work with the pan-Canadian Pharmaceutical Alliance, Federal, Provincial, and Territorial public drug plans, and private insurers to expeditiously achieve listing and reimbursement, so that eligible Canadians living with ALS can have access to ALBRIOZA as quickly and efficiently as possible.

"In Canada, prescription drugs undergo a thorough and often long review and approval process across regulatory, HTA, pricing negotiations, and formulary listing with public drug plans. In addition, private insurers have their own review and listing processes," said Chris Aiello, General Manager and Head of Canada at Amylyx. "We continue to work diligently to navigate reimbursement processes to pursue broad and equitable access to ALBRIOZA across all provinces in Canada."

"Market availability is an important milestone in the available treatment options for people living with ALS," said Tammy Moore, CEO of the ALS Society of Canada. "As we look forward, we do not want to see coverage decisions become a barrier to access, and we urge the decision-makers throughout the drug access and reimbursement process to work expeditiously to provide equitable access for all eligible Canadians living with ALS who are in desperate need."

As part of Amylyx' continued commitment to the ALS community, through the Amylyx Care Team (ACT) Support Program, Amylyx provides insurance navigation, treatment coordination and educational support for people living with ALS who have been prescribed ALBRIOZA in Canada and their caregivers. Eligibility and enrollment into the ACT Support Program can be discussed with prescribing health care professionals.

For product information, please visit www.amylyx.ca/product.

About ALBRIOZA™

ALBRIOZA™ (sodium phenylbutyrate and taurursodiol) is an oral fixed-dose medication approved with conditions to treat amyotrophic lateral sclerosis (ALS) in Canada and with marketing applications pending in the United States and European Union. The combination of sodium phenylbutyrate and taurursodiol may reduce neuronal cell death, hypothesized to occur by simultaneously mitigating endoplasmic reticulum (ER) stress and mitochondrial dysfunction. ALBRIOZA is also being explored for the potential treatment of other neurodegenerative diseases.

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 the of 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 regulatory approval of AMX0035 and the potential of AMX0035 or other future therapeutic candidates as a treatment for ALS and other neurodegenerative diseases. 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, 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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