



Amylyx Pharmaceuticals Announces Exclusive AMX0035 Distribution Agreement with Israel-Based Neopharm

January 17, 2023

- Neopharm gains exclusive rights to commercialize AMX0035 in Israel, Gaza, West Bank, and the Palestinian Authority
- Agreement marks Amylyx' first distribution partnership since AMX0035 regulatory approvals and commercial launches in the U.S. and Canada

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Amylyx Pharmaceuticals, Inc. (NASDAQ: AMLX) ("Amylyx" or the "Company") today announced it has entered into an exclusive license and distribution agreement with Neopharm in which Neopharm will commercialize, subject to regulatory review and approval, AMX0035 (sodium phenylbutyrate and ursodiol) for the treatment of amyotrophic lateral sclerosis (ALS) in Israel, Gaza, West Bank, and the Palestinian Authority.

"This agreement with Neopharm is an important step towards expanding AMX0035's availability in the EMEA (Europe, Middle East, and Africa) region, if approved," said Stéphanie Hoffmann-Gendebien, General Manager and Head of EMEA at Amylyx. "Our team remains steadfast in our mission to help every eligible person living with ALS gain access to AMX0035, and working with the right partners, such as Neopharm, will help us to reach that goal as quickly and efficiently as possible. This decision was based on a number of factors, including the ability to leverage potential approvals in other regions in the Israel Health Ministry's review process to provide access for eligible people with ALS."

ALS is a relentlessly progressive and fatal neurodegenerative disorder caused by motor neuron death in the brain and spinal cord. Motor neuron loss in ALS leads to deteriorating muscle function, the inability to move and speak, respiratory paralysis, and eventually death.

"The addition of AMX0035 to our portfolio and the opportunity to serve the ALS community in Israel and beyond is an honor," said Efi Shnaidman, General Manager of Neopharm Israel. "We look forward to working with Amylyx to serve people living with ALS who may benefit from this important new treatment option."

Under the terms of the agreement, Neopharm will receive exclusive rights to commercialize AMX0035 in the covered territory and will be responsible for all regulatory filings and obligations required for the registration and reimbursement of AMX0035.

About AMX0035

AMX0035 is an oral, fixed-dose medication approved to treat amyotrophic lateral sclerosis (ALS) in adults in the U.S. as RELYVRIO™ (sodium phenylbutyrate and taurursodiol) and approved with conditions in Canada as ALBRIOZA™ (sodium phenylbutyrate and ursodiol). Additionally, the European Medicines Agency (EMA) is reviewing the Company's Marketing Authorisation Application for AMX0035 for the treatment of ALS in Europe. AMX0035 is 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 disease 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.

About Neopharm

Established in 1941, Neopharm is one of Israel's leading providers of innovative integrated solutions across the pharmaceutical, medical and healthcare markets. Neopharm focuses on the sale and marketing of novel groundbreaking specialty and orphan medications as well as home healthcare services in Israel via partnerships with the world's leading multinational bio-pharma companies. Neopharm is the partner-of-choice and one-stop-shop for multinational bio-pharma companies seeking to enter or expand their business in the Israeli pharmaceutical, medical and biotechnology markets and is proud of its best-in-class platform, reputation and track-record of success for launching and marketing groundbreaking novel therapies in Israel.

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 plans and expectations related to the Company's exclusive distribution agreement with Neopharm; expectations regarding regulatory approvals and the ability to leverage regulatory approvals in other regions; and expectations regarding our longer-term strategy. 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 commercial and regulatory strategy, regulatory developments, expectations regarding the timing of regulatory review of AMX0035 for the treatment of ALS, Amylyx' ability to fund operations, and the impact that the ongoing COVID-19 pandemic, global macroeconomic uncertainty and geopolitical instability 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' Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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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