Market Withdrawal: Relyvrio (sodium phenylbutyrate and taurursodiol)

April 5, 2024

Amylyx Pharmaceuticals, Inc. has started a process with the U.S. Food and Drug Administration (FDA) to voluntarily discontinue the marketing authorizations for Relyvrio (sodium phenylbutyrate and taurursodiol) and remove the product from the market in the U.S. based on topline results from the Phase 3 PHOENIX trial. Relyvrio will no longer be available for new patients as of April 4, 2024. For patients currently on therapy who, in consultation with their physician, wish to continue can be transitioned to a free drug program; PHOENIX Open Label Extension is ongoing.

Relyvrio (sodium phenylbutyrate and taurursodiol) is used for amyotrophic lateral sclerosis (ALS). Topline data from PHOENIX will be presented at the American Academy of Neurology (AAN) Annual Meeting in Denver and online, taking place April 13-18, 2024. The presentation is scheduled to occur on April 16, 2024, during the Clinical Trials Plenary Session (9:15 a.m. – 11:30 a.m. MT) and will be made available on the “Publications and Presentations” section of the Company’s website following the conclusion of the presentation.

The above market withdrawal includes the following NDCs:

Product	NDC #
Relyvrio for oral suspension	73063-0035-03
	73063-0035-04

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For more information, please review the following press release: https://www.amylyx.com/news/