

## Relyvrio® (sodium phenylbutyrate/taurursodiol) - Drug discontinuation

- On April 4, 2024, <u>Amylyx Pharmaceuticals announced</u> that it has started a process with the FDA to voluntarily discontinue the marketing authorization for <u>Relyvrio</u> (<u>sodium</u> <u>phenylbutyrate/taurursodiol</u>) and remove the product from the market based on topline results from the Phase 3 PHOENIX trial.
- Relyvrio is approved for the treatment of amyotrophic lateral sclerosis (ALS) in adults.
- Amylyx's withdrawal decision follows a <u>previous announcement</u> that the PHOENIX trial, a 48week, randomized, placebo-controlled study in patients with ALS failed to meet its primary endpoint.
  - The primary endpoint in the study was the change from baseline in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) total score.
- Relyvrio will no longer be available for new patients as of April 4, 2024.
- Patients currently on therapy who, in consultation with their physician, wish to stay on treatment can be transitioned to a free drug program.



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