Relyvrio® (sodium phenylbutyrate/taurursodiol) – Drug discontinuation

- On April 4, 2024, Amylyx Pharmaceuticals announced that it has started a process with the FDA to voluntarily discontinue the marketing authorization for Relyvrio (sodium phenylbutyrate/taurursodiol) 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 previous announcement that the PHOENIX trial, a 48-week, 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.