## The Medical Letter®

### on Drugs and Therapeutics

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### on Drugs and Therapeutics

Volume 66 (Issue 1704) June 10, 2024

#### Addendum: Relyvrio Withdrawn

Relyvrio, the fixed-dose combination of sodium phenyl-butyrate and taurursodiol that received accelerated approval for treatment of amyotrophic lateral sclerosis (ALS) in 2022 based on a phase 2 trial showing that it slowed functional decline, has voluntarily been withdrawn from the market. According to the manufacturer (Amylyx), the decision to withdraw Relyvrio was based on the results of a phase 3, 48-week trial (PHOENIX). The change from baseline on the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale, which measures fine motor, gross motor, bulbar, and respiratory functioning, was not statistically significantly greater with Relyvrio than with placebo.2 Patients who are already taking the combination will be able to receive the drug from the manufacturer free of charge.

- 1. Relyvrio for ALS. Med Lett Drugs Ther 2022; 64:190.
- 2. LH van den Berg. PHOENIX. Results from a global phase 3 trial evaluating an oral, fixed-dose combination of sodium phenylbutyrate and taurursodiol in amyotrophic lateral sclerosis. Available at: https://bit. ly/4dU0mCo. Accessed May 22, 2024.

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