June 13, 2022

Amylyx announces that Health Canada has approved ALBRIOZA™ (also known as AMX0035), with conditions, for the treatment of ALS

Today Amylyx announced that Health Canada has approved ALBRIOZA™ (sodium phenylbutyrate and ursodoxicoltaurine), with conditions, for the treatment of amyotrophic lateral sclerosis (ALS). Clinical data demonstrated a statistically significant and clinically meaningful benefit in functional outcomes for people with ALS taking ALBRIOZA (also known as AMX0035) compared to people taking placebo, either as a stand-alone therapy or when added to existing treatments for ALS. This decision marks the first marketing approval for ALBRIOZA issued to Amylyx worldwide.

The approval of ALBRIOZA was authorized under Health Canada's Notice of Compliance with Conditions (NOC/c) policy. One of the conditions of the approval is the provision of data from the ongoing Phase 3 PHOENIX trial. Other conditions include additional planned or ongoing studies. Amylyx anticipates topline results from the PHOENIX trial in 2024.

The approval of ALBRIOZA is based on data from CENTAUR, a multicenter Phase 2 clinical trial in 137 participants with ALS encompassing a 6-month randomized placebo-controlled phase and an open-label long-term follow-up phase, which demonstrated that participants treated with ALBRIOZA scored, on average, 2.32 points higher on the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFRS-R) over a period of 24 weeks. Detailed data from CENTAUR were published in the New England Journal of Medicine, Muscle & Nerve, and the Journal of Neurology, Neurosurgery, and Psychiatry.

Detailed safety and functional efficacy data from CENTAUR were published in the New England Journal of Medicine. Data from additional analyses from the CENTAUR trial were published in Muscle & Nerve in 2020 and 2022, and the Journal of Neurology, Neurosurgery and Psychiatry in 2022.

In the European Union, the Company’s Marketing Authorisation Application for AMX0035 is under review by the European Medicines Agency, and a regulatory decision is expected in the first half of 2023.

European organization for Professionals and Patients with ALS (EUpALS) ivzw
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