

Poor trial results may prompt maker to pull ALS drug from market

March 11 2024, by Robin Foster



Following disappointing trial results, the maker of a controversial ALS drug may pull the medication off the market.

In a [statement](#) issued Friday, Amylyx Pharmaceuticals said that Relyvrio failed to help patients in a large follow-up study, but the company stopped just short of saying it will definitely pull the drug from the market. The drug is sold as Albrioza in Canada.

"Amylyx intends to share plans for Relyvrio/Albrioza in ALS, which may include voluntarily withdrawing Relyvrio/Albrioza from the market," the company said in its statement. "At this time, Relyvrio/Albrioza and its related patient support program will continue to be available for people living with ALS. Amylyx has voluntarily decided to pause promotion of the medication during this time."

Executives added that they were "surprised and disappointed" by the results and would announce their plans for the drug in the next two months.

Relyvrio was first [approved](#) by the U.S. Food and Drug Administration in September 2022, following a lengthy, impassioned campaign by patients with ALS, a fatal muscle-wasting disease.

Unfortunately, the latest company study showed the drug did not slow the disease compared with a placebo treatment, and it also did not produce improvements on any secondary measures, such as muscle strength.

ALS is a devastating neurological disease slowly destroys [nerve cells](#) and connections that are needed to walk, talk, speak and breathe. Most patients die within three to five years of their diagnosis.

Relyvrio's approval was mainly based on results from one small study that was criticized by some of the FDA's scientists. An outside committee of experts also [voted against the drug](#) initially, before being swayed to back it at a [follow-up meeting](#) requested by patients. At the

time, Amylyx noted it was continuing a larger follow-up study of more than 600 patients that would provide further data on the drug.

In a highly unusual move, Amylyx executives at that second advisory committee meeting told FDA regulators they would pull the drug from the [market](#) if follow-up research didn't confirm its efficacy. That commitment seemed to reassure FDA's advisers, who then voted in favor of [the drug's approval](#), despite the questionable data.

Amylyx has also faced criticism for pricing the drug at \$158,000 for a year's supply, the Associated Press reported, and sales have been lackluster since Relyvrio's launch in late 2022.

Relyvrio combines two older drugs: a [prescription medication](#) for liver disorders and a [dietary supplement](#) associated with traditional Chinese medicine.

More information: The ALS Association has more on [ALS](#).

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