Highly awaited Alzheimer's drug hit by delays

March 8 2024

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Eli Lilly's highly anticipated Alzheimer's drug has been held back for further review by regulators, the US pharmaceutical giant said Friday, in a blow for patients with the devastating brain disorder.

Donanemab has been found to slow cognitive decline in the early stages

of the disease during a clinical trial—but there was also a high rate of side effects, including deaths.

The Food and Drug Administration (FDA) "has informed Lilly it wants to further understand topics related to evaluating the safety and efficacy of donanemab," the company said in a statement Friday.

The regulator told the Indiana-based company it would convene a new meeting of experts, but hadn't provided a firm date. "As a result, the timing of expected FDA action on donanemab will be delayed beyond the first quarter of 2024."

"We are confident in donanemab's potential to offer very meaningful benefits to people with early symptomatic Alzheimer's disease," said Anne White, the company's executive vice president.

She added the FDA's decision to have a new meeting was "unexpected," but "We will work with the FDA and the stakeholders in the community to make that presentation and answer all questions."

Donanemab is an intravenously injected antibody that targets the build up beta-amyloid, a protein found in the brains of many patients with Alzheimer's.

Another anti-amyloid therapy called Leqembi, which was developed by Eisai of Japan and Biogen of Massachusetts, was granted full approval by the FDA last July and is now accessible through government-run health insurance for the elderly called Medicare.

Slows decline, but risky

In a paper published in the *Journal of the American Medical Association* last year, researchers found donanemab slowed cognitive and functional

decline in patients who have early symptoms of the disease.

Forty-seven percent of those who received the drug showed no signs of cognitive decline after one year of treatment, compared to 29 percent who received a placebo.

Serious adverse events, including brain bleeds, occurred in 17.4 percent of those who received donanemab and 15.8 percent of those who received a placebo.

There were also four deaths: three in the donanemab group and one in the placebo group, but all the fatalities were considered a result of the treatment they received.

The donanemab trial recruited participants aged 60 to 85 with early symptomatic Alzheimer's, either mild cognitive impairment or Alzheimer's disease with mild dementia.

Over-hyped?

"The delay in granting a US license is a major blow for Lilly and their amyloid antibody donanemab and is based on concerns about the brain swelling and bleeding seen with the drug," said Robert Howard, a professor of old age psychiatry at the University College London.

"These side-effects are about twice as common with donanemab than with Eisai's drug lecanemab which already has a license in the US," he added.

"The balance between the modest benefits of the amyloid antibody treatments for Alzheimer's disease and the risks that they carry is under ever closer scrutiny as the gap between the hype and reality around these drugs narrows."

The US Alzheimer's Association said it "appreciates" the FDA for being thorough and agreed safety was paramount.

"On behalf of everyone who could benefit from this treatment, we strongly urge the FDA to move swiftly in this next stage of its review," the group said.

The news comes after the first Alzheimer's drug to be approved was pulled from the market in January.

The FDA awarded accelerated approval to Aduhelm in June 2021, a decision that was contentious at the time because the agency overruled its own independent advisors, who found there was insufficient evidence of benefit.

Biogen, which co-developed Aduhelm with Eisai, said it was discontinuing Aduhelm to focus its efforts of Leqembi.

Alzheimer's is the most common form of dementia. More than one in nine people over 65 develop the condition, which worsens over time, robbing them of their memories and independence.

Citation: Highly awaited Alzheimer's drug hit by delays (2024, March 8) retrieved 27 April 2024 from https://medicalxpress.com/news/2024-03-highly-awaited-alzheimer-drug-delays.html