Biogen pulls controversial Alzheimer's drug Aduhelm

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Biogen said it was discontinuing Aduhelm to put more resources into Leqembi, a newer Alzheimer's medicine that was fully approved in 2023 under the traditional regulatory pathway.

A controversial Alzheimer's drug that was trumpeted as the first to ever treat the cognitive decline associated with the devastating brain disorder

has been pulled from the market, its maker Biogen announced Wednesday.

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

At least three of the 11-member independent committee that voted unanimously against recommending the drug subsequently resigned, and US congressional investigators slammed the accelerated approval as "rife with irregularities."

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"When searching for new medicines, one breakthrough can be the foundation that triggers future medicines to be developed," said Christopher Viehbacher, president and CEO of the Cambridge, Massachusetts-based biotech firm.

"Aduhelm was that groundbreaking discovery that paved the way for a new class of drugs and reinvigorated investments in the field."

Aduhelm, a monoclonal antibody that targets the build-up of a protein called amyloid beta in the brain tissue which is thought to be a cause of Alzheimer's, was tested in two late-stage human trials.

It showed a reduction in cognitive decline in one of the studies, but not the other.

According to a congressional report from December 2022, the FDA

"considered Aduhelm under the traditional approval pathway used for most drugs for nine months, before abruptly changing course and granting approval under the accelerated approval pathway after a three-week review period."

The report said that FDA interactions with Biogen were "atypical" and included a failure to properly document contacts between agency staff and the drug maker.

The FDA and Biogen had also "inappropriately collaborated" on a joint briefing document for a key advisory committee, it said.

"FDA's approval process was rife with irregularities."

As for Biogen, the report said the company "viewed Aduhelm as an unprecedented financial opportunity—estimating a potential peak revenue of $18 billion per year."

The congressional panel pointed to an "unjustifiably high price" for Aduhelm of $56,000 a year for patients.

Biogen's Leqembi, which it co-manufactures with Eisai of Japan, is now the only US approved treatment for Alzheimer's. It also targets amyloid beta and has been found to modestly reduce cognitive decline in patients with early stage disease.

Donanemab, developed by Eli Lilly, could be next to get the green light after performing similarly in clinical trials.

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, according to the US Alzheimer's Association.