**Controversial Alzheimer's Drug Abandoned** — Biogen will stop developing and selling aducanumab

Biogen will discontinue its controversial Alzheimer's drug aducanumab (Aduhelm), the [company announced](https://investors.biogen.com/news-releases/news-release-details/biogen-realign-resources-alzheimers-disease-franchise) Wednesday. The drugmaker will stop developing and selling aducanumab, an anti-amyloid monoclonal antibody that received FDA [accelerated approval](https://www.medpagetoday.com/neurology/alzheimersdisease/92960) in 2021. Biogen also will terminate the confirmatory ENVISION trial, which was a requirement of its accelerated approval.

Aducanumab was the first approved treatment that targeted Alzheimer's pathophysiology. The drug raised considerable controversy in the wake of findings from 2 identical phase III studies, EMERGE and ENGAGE. The trials were terminated in March 2019 when a futility analysis determined aducanumab was unlikely to outperform placebo at completion. In October 2019, Biogen reversed its position, saying a review of previously unavailable data showed the drug reduced cognitive decline in EMERGE, but not in ENGAGE.

In November 2020, an FDA [advisory committee voted overwhelmingly against](https://www.medpagetoday.com/neurology/alzheimersdisease/89544) the aducanumab trial data Biogen presented, saying the positive results seen in one trial could not be considered alone but must be taken together with its twin, which clearly was negative. After aducanumab received accelerated approval, [Medicare limited coverage](https://www.medpagetoday.com/neurology/alzheimersdisease/98116) of the drug.

A 2022 congressional investigation reported that the [FDA broke with its own protocols](https://www.medpagetoday.com/washington-watch/fdageneral/102464) in reviewing and approving aducanumab by inappropriately collaborating with Biogen on briefing documents, holding unreported meetings, and failing to gain internal consensus before engaging in these collaborations.

Since aducanumab's approval, 2 other anti-amyloid drugs demonstrated better clinical outcomes in phase III trials: lecanemab (Leqembi), which [received full FDA approval](https://www.medpagetoday.com/neurology/alzheimersdisease/105364) in 2023, and [donanemab](https://www.medpagetoday.com/meetingcoverage/aaic/105515" \o "Opens in a new tab or window" \t "_blank), an investigational drug from Eli Lilly. Biogen is partnered with the Japanese pharmaceutical company Eisai on lecanemab. "As a pioneer in Alzheimer's disease, Biogen is reprioritizing resources to build a leading franchise to address the multiple pathologies of the disease and patient needs," Christopher Viehbacher, Biogen's president and chief executive officer, said in a statement. "We plan to further advance the launch of Leqembi, together with Eisai, and continue to bolster innovation with the development of the other assets in our pipeline." Those assets include an antisense oligonucleotide targeting tau expression known as BIIB080 and an oral small molecule inhibitor of tau aggregation called BIIB113.

The decision to stop marketing aducanumab was not related to any safety or efficacy concerns, Biogen said. A large part of the money freed up by stopping the aducanumab program is expected to be used to build the company's Alzheimer's franchise. "When searching for new medicines, one breakthrough can be the foundation that triggers future medicines to be developed," Viehbacher noted. "Aduhelm was that groundbreaking discovery that paved the way for a new class of drugs and reinvigorated investments in the field."

Global [rights to aducanumab](https://www.neurimmune.com/news/neurimmune-to-regain-global-rights-to-brain-amyloid-depleter-for-the-treatment-of-alzheimers-disease) have reverted to Neurimmune, the Swiss-based company that developed the drug and licensed it to Biogen.