Biogen Abandons Its Controversial Alzheimer's Drug Aduhelm

The pharmaceutical company will give up its ownership rights to the drug and stop a clinical trial that had been aimed at confirming whether it works.

Biogen's decision to abandon its ownership rights to Aduhelm closes out a yearslong saga that generated outrage and eroded trust in the regulatory process for bringing new medicines to market. Pool photo by Jessica Rinaldi

By Rebecca Robbins

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The drug maker Biogen said on Wednesday it would abandon its ownership rights to Aduhelm, an Alzheimer's drug that had provoked fierce criticism of the company and regulators after it was approved based on weak evidence that it would help patients.

The company will also stop a clinical trial that the Food and Drug Administration had ordered to confirm whether the drug is effective in slowing the progression of Alzheimer's disease.

With an initial sticker price of $56,000 a year, Aduhelm was once projected to be taken by millions of Alzheimer's patients, strain Medicare's budget and bring in billions of dollars a year. But Aduhelm failed spectacularly in the marketplace.

Biogen's decision closes out a yearslong saga that generated outrage and eroded trust in the regulatory process for bringing new medicines to market. One F.D.A. adviser called the approval of the drug perhaps "the worst approval decision that the F.D.A. has made that I can remember." A congressional inquiry later found that the F.D.A.'s process for approving Aduhelm had been "rife with irregularities" and involved "lapses in protocol," including unusually close collaboration with Biogen.

Doctors also worried about the drug's serious safety risks, especially in light of its uncertain benefit. Aduhelm can cause brain swelling or brain bleeding.

The concerns were so great that Medicare moved to sharply limit coverage of Aduhelm, making it available only to patients in clinical trials. Medicare covers Alzheimer's drugs with full approval, which Aduhelm lacked.

Aduhelm brought in only $7.8 million in its first year and a half on the market. Since then, Biogen's revenue from the drug has been so small that the company no longer reports the details.

Biogen said on Wednesday that it was not acting because of any concerns about the drug's safety or effectiveness. Now, the rights to Aduhelm will go back to the Swiss company Neurimmune, which had licensed the drug to Biogen.

Biogen will continue to supply monthly infusions of the drug to patients in the commercial market until November and to those in the confirmatory clinical trial until May. On Nov. 1, Biogen's license to sell the drug in the United States will be withdrawn.

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Since it was approved, Aduhelm has been supplanted by two Alzheimer's drugs that have shown evidence that they can somewhat slow cognitive decline but that doctors say may not have a significant enough effect to be noticeable to patients or families.

Biogen and its partner, Eisai, a Japanese pharmaceutical company, won approval last year for a drug, Leqembi, that is gradually being prescribed to more patients. Eli Lilly is expected to win approval soon for another drug, donanemab.

Pam Belluck contributed reporting.

A correction was made on Jan. 31, 2024: *An earlier version of this article referred incorrectly to Biogen's timeline for supplying the drug Aduhelm to patients in its confirmatory clinical trial. Patients will be prescribed the drug until May, not through the month.*

When we learn of a mistake, we acknowledge it with a correction. If you spot an error, please let us know at nytnews@nytimes.com. Learn more

Rebecca Robbins is a reporter covering the pharmaceutical industry. She has been reporting on health and medicine since 2015. More about Rebecca Robbins

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