

# Lilly to seek FDA approval for new Alzheimer's drug

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Fresh on the heels of the U.S. Food and Drug Administration's approval

of the controversial Alzheimer's drug Aduhelm, the maker of a second medicine that works in similar fashion said Thursday it hopes to apply for approval of its medication later this year.

Eli Lilly said findings from a mid-stage clinical trial of 272 patients with early Alzheimer's suggest the [drug](#) donanemab slows declines in thinking and daily function, the *Associated Press* reported.

The company said it plans to examine the drug in a larger, late-stage trial that will complete enrollment by the end of the year, followed by an 18-month treatment period.

Donanemab has already received a "breakthrough therapy" designation from the FDA, which is meant to hasten development and review of drugs considered to be potentially better than existing treatments. Donanemab, like Aduhelm, clears an Alzheimer's-linked protein called beta-amyloid from the brain.

Lilly may be able to file its application for approval in the next two or three months since the drugmaker appears to have all the data it needs, Dr. Vamil Divan, an analyst who covers the company for Mizhuho Securities U.S., told the *AP*.

Just a few weeks ago, the FDA approved Aduhelm from Biogen, over the objections of independent advisers who said the drug hasn't been shown to help slow Alzheimer's. The FDA said it was "reasonably likely" that Aduhelm would help patients, the *AP* reported.

Aduhelm—the first new Alzheimer's drug approved in the United States in nearly 20 years—is the only treatment likely capable of changing the course of the disease, rather than slowing symptoms like thinking/memory problems and anxiety, U.S. regulators said at the time.

On Wednesday, Biogen said another experimental Alzheimer's drug it developed with Eisai Co. was given breakthrough designation by the FDA, and that the drug, lecanemab, is being assessed in a late-stage study, the *AP* reported.

Some 6 million Americans and many more worldwide have Alzheimer's disease, which slowly damages areas of the brain needed for memory, reasoning, communication and basic daily tasks.

Lilly and several other drugmakers have previously failed in attempts to find a treatment that slows the progression of the mind-robbing disease.

More than four years ago, Lilly said another potential drug it developed called solanezumab did not work better than a placebo in a study of over 2,100 people. That drug also aimed to clear potentially harmful protein from the brain.

**More information:** Visit the [Alzheimer's Association](#) for more on Alzheimer's disease.

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