

Video: Expert provides perspective on FDA approval of another experimental Alzheimer's drug

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The Food and Drug Administration (FDA) granted accelerated approval of a disease-modifying treatment that could potentially give some

patients with Alzheimer's disease something they haven't had before: a medication that may slow the decline of memory and thinking.

A monoclonal antibody, lecanemab, shows promise in removing [amyloid plaques](#) from the brain, according to phase 3 trial results. Amyloid plaques are one of the defining features of Alzheimer's disease, according to Dr. Ronald Petersen, a neurologist and director of the Mayo Clinic Alzheimer's Disease Research Center.

"Amyloid is one of the key proteins involved in Alzheimer's disease. It's thought that by removing [amyloid](#) from the brain, you will slow down the rate of progression of the disease. Now, importantly, it doesn't stop the disease. It doesn't make people better, but it will slow down the rate at which the disease progresses so people remain functional for a longer period of time," says Dr. Petersen.

Brain changes associated with Alzheimer's disease can lead to growing trouble with:

- Memory
- Thinking and reasoning
- Making judgments and decisions
- Planning and performing familiar tasks
- Changes in personality and behavior

"The accelerated approval part means that while they're convinced it does what it's supposed to do, biologically, they're not convinced of the clinical meaningfulness of that. That is, if you lower amyloid in the brain of a person with Alzheimer's disease, does that make any clinical difference? They're uncertain of that so they require the sponsor to gather more data," Dr. Petersen says.

Phase 3 data, reported in late November, will be submitted to the FDA

later this year for full approval.

Dr. Petersen says it's important to note that this treatment is not intended for all dementia patients, only those who have [mild cognitive impairment](#) or mild dementia due to Alzheimer's disease.

As with any drug, Dr. Petersen says lecanemab has potential side effects which can be serious.

"Lecanemab does, in fact, remove amyloid from the brain, but it may also remove amyloid from the [blood vessels](#) in the brain," he explains. "This may render them leaky, such that people on this drug may develop some swelling in the brain and may develop some bleeding in the [brain](#). This can be monitored by MRI, and usually the side effects have been mild and moderate."

Dr. Petersen says the data from the lecanemab study were an important step forward in the fight against a disease which robs patients of their most human qualities.

"It shows that we now may have the ability to actually modify the underlying disease process. Heretofore, we've had symptomatic drugs for Alzheimer's disease, but they do not actually get at the underlying disease process. Drugs like lecanemab now actually alter the disease process itself and will slow down the rate of progression. That's a major step forward," says Dr. Petersen.

"This gives us an opportunity to perhaps add other drugs that may have additive mechanisms of action to actually slow down the disease process even more dramatically."

Provided by Mayo Clinic

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