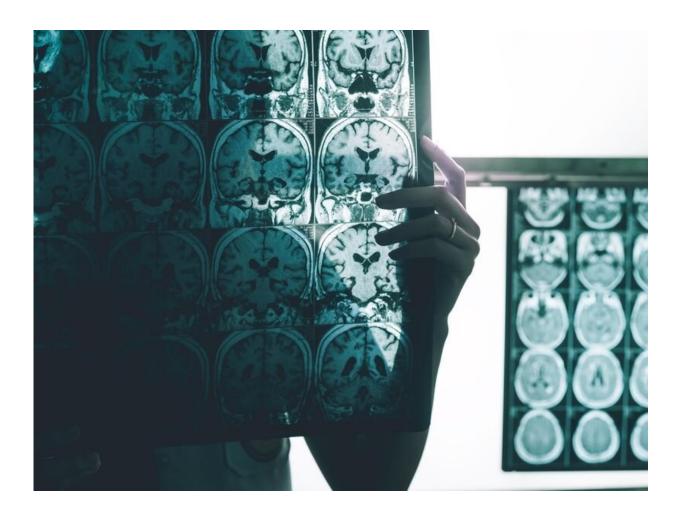


New Alzheimer's drug shows promise in phase 3 clinical trial

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Japanese drugmaker Eisai on Wednesday said its experimental drug



lecanemab helped slow thinking declines among people in the early stages of <u>Alzheimer's disease</u>.

The findings from a phase 3 clinical trial have yet to be peer-reviewed in any medical journal. But according to a company <u>news release</u>, "lecanemab treatment met the primary endpoint and reduced clinical decline on the global cognitive and functional scale, CDR-SB, compared with placebo at 18 months, by 27%."

Given the largely disappointing rollout of Biogen's Alzheimer's drug, <u>Aduhelm</u>, last year, any drug which appears to help Alzheimer's patients is welcome. But expert reaction to the Eisai announcement was mixed.

In a <u>statement</u>, Dr. Joanne Pike, president of the Alzheimer's Association, called the results an "exciting major development."

"These are the most encouraging results in <u>clinical trials</u> treating the underlying causes of Alzheimer's to date," she said. "These results indicate lecanemab may give people more time at or near their full abilities to participate in daily life, remain independent and make future health care decisions."

But another expert offered a more muted response.

Dr. Alberto Espay, a neurologist at the University of Cincinnati College of Medicine, told *NBC News* that the benefit seen with lecanemab was "small" and added it might not translate to meaningful improvements for patients. Still, Espay believes "patients can view this [new development] with cautious optimism."

The new trial included almost 1,800 patients with early-stage Alzheimer's disease whose progress was tracked over 18 months. Investigators tracked cognition using what's known as the the <u>CDR-SB</u>



scale, which Eisai said is "used to quantify the various severity of symptoms of dementia."

"Based on interviews of people living with Alzheimer's disease and family/caregivers, qualified healthcare professionals assess cognitive and functional performance in six areas: memory, orientation, judgment and problem-solving, community affairs, home and hobbies, and personal care," the company explained.

Patients enrolled in trials based in the United States were ethnically diverse, Eisai noted, with 25% of participants being either Black or Hispanic.

Compared to patients taking a placebo "dummy" pill, those who got <u>lecanemab</u> saw a "significant" slowing of cognitive decline as measured by the CDR-SB scale, Eisai reported. Noticeable changes in the rate of decline began as early as six months after taking the drug.

PET scans of the brains of patients who took lecanemab also showed noticeable declines in levels of the <u>amyloid protein plaques</u>, which have long been a hallmark of Alzheimer's disease, Eisai noted.

As to possible side effects, there was a slight uptick in drug users of cerebral hemorrhages known as "amyloid-related imaging abnormalities" (ARIA), with 21.3% of lecanemab users experiencing this issue, compared to 9.3% of those who took the placebo.

Lecanemab is a <u>monoclonal antibody drug</u> that's designed to target and help remove Alzheimer's-associated amyloid plaques in the brain. According to Eisai, in July the drug was placed on an "accelerated approval pathway and granted priority review" by the U.S. Food and Drug Administration. That may help speed the <u>drug</u>'s path to approval.



Eisai plans to present the full phase 3 clinical trial data in late November "at the Clinical Trials on Alzheimer's Congress [CTAD], and publish the findings in a peer-reviewed medical journal," the company said.

However, Alzheimer's patients and their caregivers have had their hopes raised in the past—only to be let down later.

Aduhelm also works by reducing <u>amyloid plaques</u> in the brain, but its approval by the FDA was contentious because amyloid reductions didn't seem to translate to significant improvements in daily function or any real slowing of disease.

Some scientists have begun to move away from an "amyloid-centered" approach to Alzheimer's treatment altogether.

Pike agreed that the full verdict on lecanemab is not yet in.

"We will know more at the end of November when the data behind these initial results will be public," she said. "We look forward to learning more at that time about participant safety and representation in the trials. It's also important to manage our own expectations that this treatment is not yet Food and Drug Administration [FDA]-approved and is not yet available in doctors' offices."

Still, Pike believes the new findings offer much needed hope.

"This is a major milestone for Alzheimer's disease treatments," she said. "It is a significant gain for people with the disease and their families, and it further positions us to advance our mission in new and exciting ways."

More information: Find out more about Alzheimer's disease at the <u>Alzheimer's Foundation</u>.



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