

Lilly presents trial data on Alzheimer's drug showing promise

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Eli Lilly & Co. presented highly anticipated details from a mid-stage study showing that its experimental drug modestly slowed Alzheimer's disease progression over about 18 months.

The study of 257 patients with early Alzheimer's showed that Lilly's donanemab slowed decline by 32% on a composite measure of cognition and function when compared with a placebo. It also completely removed an Alzheimer's-associated protein from the brains of the majority of patients who received it.

The results are being watched closely by Wall Street analysts and researchers for a hint of whether donanemab—or any other drugs that eliminate amyloid, a tell-tale protein that accumulates in Alzheimer's patients' brains—will finally work. Over the years, numerous other candidates have aimed at amyloid only to yield confusing or negative results in big human [trials](#).

Lilly's results appear to be more straightforward than many previous studies, said Marwan Sabbagh, director of translational research at the Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas.

"I have been in this field a long time," Sabbagh, who wasn't involved in the study, said Saturday in an interview prior to the presentation. "This is some of the best phase 2 data I have seen, hands down."

Lilly first announced the top-line results in January, sending its stock soaring, but the virtual presentation Saturday at the International Conference on Alzheimer's & Parkinson's Diseases meeting is their first detailed unveiling. The trial data is also being published contemporaneously in the New England Journal of Medicine.

On secondary goals of the study, including certain other dementia rating scales that have been commonly used in other Alzheimer's trials, the findings weren't as clear-cut. While patients on the [drug](#) did numerically better on these various other scales compared to placebo, the differences weren't statistically significant in some cases.

"Results for secondary outcomes were mixed," researchers from Lilly, Brown University, and the Indiana University School of Medicine concluded in the journal article. Longer, larger trials are required to further understand the drug's effects and side-effect profile, they said.

Given the number of previous Alzheimer's trial failures, "I was surprised and impressed by these results," said David Knopman, a neurologist and dementia researcher at the Mayo Clinic in Rochester, Minnesota. He called it "a small but significant clinical benefit" and said the finding needs to be confirmed in another trial.

Key unknowns include whether the benefit lasts over the long term, and whether patients and caregivers would consider that modest benefit to be meaningful, Knopman said. He wasn't involved in the trial, but has been involved in studies of other Lilly Alzheimer's drugs.

Side effects of the Lilly drug in the trial included brain swelling spotted on imaging scans, drug-infusion reactions and nausea.

For more than a year, the Alzheimer's disease field has been consumed by another drug that targets amyloid, Biogen Inc.'s aducanumab. Until the Lilly results came along, the Biogen drug was viewed as one of the last hopes for anti-amyloid therapies.

Trials of that drug have produced confusing results that have sharply divided Alzheimer's disease researchers. It's under review by the U.S. Food and Drug Administration, which is scheduled to make a decision by June.

In the donanemab study, Lilly treated Alzheimer's patients like an oncologist might stage and treat cancer, Lilly Chief Scientific Officer Daniel Skovronksy said in an interview before the presentation. They selected a subset of patients with high amyloid levels and middling levels

of tau, a second abnormal protein linked to brain-cell death. The goal was to study patients who weren't too late in the disease to treat, yet were affected enough to show a benefit if the drug worked, he said.

"This is a really profound effect that appeared early," he said. "We are in discussions with regulators around the world about this data."

He declined to go into details about next steps for the drug. Lilly has another efficacy trial of the therapy ongoing.

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