

## Alzheimer's drug fails study but flashes potential

24 August 2012, by TOM MURPHY

(AP)—An Alzheimer's treatment from Eli Lilly and Co. failed to slow memory decline in two separate patient studies, but the drug did show some potential to help in mild cases of the mind-robbing condition that is notoriously difficult to treat.

The Indianapolis drugmaker's announcement could be a step toward a long-awaited breakthrough in the fight against the disease. But researchers not tied to the studies—and Eli Lilly itself—cautioned against overreacting to the initial results.

Lilly said Friday that its treatment, solanezumab, failed to slow the rate of cognitive decline, which involves a person's ability to remember things, in two late-stage studies of about 1,000 patients each. But when data from the trials were combined, scientists saw a statistically significant slowing of that rate in the bigger population.

They also saw a statistically significant result when they examined a subgroup of patients with mild cases of Alzheimer's disease. The studies focused on patients with mild to moderate Alzheimer's cases.

Lilly officials would not discuss details of the results and said that they plan to talk with regulators about Many Alzheimer's patients typically live four to eight the next steps for the drug, which has yet to receive Food and Drug Administration approval. Full results from the studies will be presented at two scientific conferences in October. It's unclear how the FDA will view the results, given that the drug missed its main goals.

William H Thies, chief medical and scientific officer for the Alzheimer's Association, which was not involved in Lilly's research, said the statistical significance of the combined results is important.

"If that can be replicated, that is a major finding," he said. "It's the first time we've been able to change the course of Alzheimer's disease or any part of Alzheimer's disease in people."

But because the drug missed its main goals, Thies said the drug "isn't going to the (FDA) tomorrow to be approved for sale."

If you look through "rose-colored glasses" at the results, there may be a sign of potential benefit on cognitive tests, said Dr. Ronald Petersen, director of the Mayo Clinic's Alzheimer's Disease Research Center. But it is not clear whether that is enough to make a real difference clinically in how patients do, he said.

The key will be details the company will present later on brain imaging and other tests, he said.

"The danger would be an over-interpretation of a small finding or a subtle effect," said Petersen, who heads a safety monitoring panel for two companies working on a different Alzheimer's treatment.

About 35 million people worldwide have dementia, a term for brain disorders that affect memory. judgment and other mental functions. Alzheimer's is the most common type. In the United States, more than 5 million people have Alzheimer's, which is the country's sixth-leading cause of death.

years after diagnosis, as the disease gradually erodes their memory and ability to think or perform simple tasks. Current Alzheimer's treatments only temporarily ease symptoms such as memory loss, confusion and agitation. They don't slow, stop or reverse mental decline.

Drugmakers have tried and failed for years to develop successful treatments for the disease, and patients and doctors are anxious for something that can slow the disease's progression. Analysts have said such a treatment, if approved, could be worth billions of dollars in sales.

AP Chief Medical Writer Marilynn Marchione in Milwaukee contributed to this report.



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