

Lilly plans another study for Alzheimer's drug (Update)

December 12 2012, by Tom Murphy

Eli Lilly's experimental Alzheimer's drug has flashed potential to help with mild cases of the disease, but patients and doctors will have to wait a few more years to learn whether regulators will allow the drugmaker to sell it.

Lilly said Wednesday that it will launch another late-stage study of the drug, solanezumab, no later than next year's third quarter. The company's stock slipped in midday trading.

The Indianapolis drugmaker said in August that the intravenous treatment failed to slow memory decline in two late-stage studies of about 1,000 patients each. But scientists saw a statistically significant slowing when they combined trial data. Pooled results found 34 percent less mental decline in mild Alzheimer's patients compared with those on a fake treatment for 18 months.

Researchers also saw a statistically significant result when they examined a subgroup of patients with mild cases of Alzheimer's disease.

Lilly will attempt to confirm that benefit in the new trial before it seeks U.S. regulatory approval, something analysts widely expected the drugmaker to do after it announced the initial results.

The additional study could help Lilly build a better case with U.S. regulators. But it will likely take a few years to learn the results. Researchers will have to measure over time a patient's rate of cognitive

decline, which involves the ability remember things.

Citi analyst Andrew Baum said in a research note the study will likely be completed by the second half of 2015. He expects the drug, if approved, to launch in 2017.

Eli Lilly and Co.'s share price fell \$1.60, or 3.2 percent, to close at \$49. It's still up 16 percent since the company announced the initial results in August. Baum said Wednesday's news helped shake out some of the "false hope" for a near-term approval of the drug that had inflated the stock price.

Drugmakers have tried and failed for years to develop successful treatments for Alzheimer's, and patients and doctors are anxious for something that can slow its progression.

Solanezumab was one of three potential Alzheimer's drugs in late-stage testing. Bapineuzumab, being developed by Pfizer Inc. and Johnson & Johnson's Janssen Alzheimer Immunotherapy unit, gave disappointing results in two studies last summer.

A pivotal study of the third—Gammagard, by Baxter International Inc.—will wrap up at the end of this year. Results are expected in the first or second quarter next year.

Solanezumab binds to beta-amyloid protein, which scientists believe is a key component to sticky plaque that basically gums up the brain of a patient with Alzheimer's disease. The drug is designed to help the body remove the protein from the brain before it can form that plaque.

Current treatments like Pfizer Inc.'s Aricept try to control symptoms of the disease. Analysts have said a treatment that does more than manage symptoms such as memory loss, confusion and agitation could be worth

billions of dollars in annual sales. But drugmakers first have to spend a massive amount on testing and clinical development to produce such a drug.

"When you go for the blockbuster, you have to pay for the blockbuster, either in money or time," WBB Securities analyst Steve Brozak said regarding Lilly's announcement.

More than 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. Many Alzheimer's patients typically live four to eight years after diagnosis, as the disease gradually erodes their memory and ability to think or perform simple tasks.

In the United States, 5.4 million people have Alzheimer's, which is the country's sixth-leading cause of death. The number of Alzheimer's patients in the U.S. is expected to jump to 16 million by 2050, and costs for care are expected to skyrocket.

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