



November 23, 2016

Lilly Announces Top-Line Results of Solanezumab Phase 3 Clinical Trial

INDIANAPOLIS, Nov. 23, 2016 /CNW/ -- Eli Lilly and Company (NYSE: LLY) today announced that solanezumab did not meet the primary endpoint in the EXPEDITION3 clinical trial, a phase 3 study of solanezumab in people with mild dementia due to Alzheimer's disease (AD).

Patients treated with solanezumab did not experience a statistically significant slowing in cognitive decline compared to patients treated with placebo ($p=.095$), as measured by the ADAS-Cog₁₄ (Alzheimer's Disease Assessment Scale-Cognitive subscale).

While the study results, including many secondary clinical endpoints, directionally favored solanezumab, the magnitudes of treatment differences were small. There were no new safety signals identified in the study. Lilly will not pursue regulatory submissions for solanezumab for the treatment of mild dementia due to Alzheimer's disease.

"The results of the solanezumab EXPEDITION3 trial were not what we had hoped for and we are disappointed for the millions of people waiting for a potential disease-modifying treatment for Alzheimer's disease," said John C. Lechleiter, Ph.D., chairman, president and chief executive officer, Lilly. "We will evaluate the impact of these results on the development plans for solanezumab and our other Alzheimer's pipeline assets."

Lilly will work with investigators to appropriately conclude the open-label extensions for EXPEDITION, EXPEDITION2 and EXPEDITION3. The next steps for the remaining elements of the solanezumab development program have not yet been determined.

"Lilly is grateful for the dedication of the patients, their families, and the clinical investigators who participated in this study," said Jan Lundberg, Ph.D., executive vice president of science and technology and president of Lilly Research Laboratories. "Lilly remains committed to Alzheimer's research as we have been for nearly 30 years, and our portfolio includes many other promising approaches."

Lilly will present further findings from the study at the Clinical Trials on Alzheimer's Disease (CTAD) meeting on Thursday, December 8th at 9:15 p.m. ET. The presentation will be shared live via webcast from the meeting. To access the webcast, please visit <http://www.ctad-alzheimer.com>.

"Lilly has strong growth prospects without solanezumab," said David A. Ricks, Lilly's incoming chief executive officer and president of Lilly Bio-Medicines. "Driven by new product launches, we continue to expect to grow average annual revenue by at least 5 percent between 2015 and 2020. Over that time frame, we also expect to increase our margins and provide annual dividend increases to our shareholders."

The EXPEDITION3 study outcome is expected to result in a fourth-quarter charge of approximately \$150 million (pre-tax), or approximately \$0.09 per share (after-tax). The company will provide updated 2016 financial guidance and announce its 2017 financial guidance on December 15, 2016 and will also conduct a conference call with the investment community and media at 9:00 a.m. ET on that date, instead of on the originally-scheduled date of January 4, 2017.

About Solanezumab

Solanezumab is Lilly's phase 3 monoclonal antibody being studied as a potential therapy for people with mild cognitive impairment due to Alzheimer's disease (EXPEDITION-PRO), preclinical Alzheimer's disease (Anti-Amyloid Treatment in Asymptomatic Alzheimer's "A4"), and Dominantly Inherited Alzheimer's Disease ("DIAN").

About EXPEDITION3

EXPEDITION3 is a multinational, phase 3 trial of solanezumab in more than 2,100 patients diagnosed with mild dementia due to Alzheimer's disease. The study includes an 18-month placebo-controlled period followed by an open label extension. Enrollment was completed in 2015 and the last patient visit for the placebo-controlled period occurred in October 2016.

EXPEDITION3 is the first phase 3 trial to evaluate only people with mild dementia due to Alzheimer's disease.

About Alzheimer's Disease

Alzheimer's disease is a fatal illness that is believed to start with changes in the brain that may begin 20 years or more before symptoms appear.¹ Those changes cause a progressive decline in memory and other aspects of cognition that eventually lead to dementia.

Dementia due to Alzheimer's disease is the most common form of dementia, accounting for 60 to 80 percent of dementia cases.¹ There are currently an estimated 47 million people living with dementia worldwide.² The number of people affected by dementia is expected to be nearly 75 million in 2030 and 131 million in 2050.² Estimates vary, but experts suggest that as many as 5.4 million Americans may have Alzheimer's disease.¹

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels. P-LLY

This press release contains certain forward-looking statements about solanezumab, an anti-amyloid monoclonal antibody in clinical testing for treatment of Alzheimer's disease, and the company's anticipated future results. These statements reflect Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. For further discussion of these and other risks and uncertainties and additional information about the factors that could cause actual results to differ materially from forward-looking statements, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

¹ Alzheimer's Association. 2016 Alzheimer's Disease Facts and Figures. http://www.alz.org/documents_custom/2016-facts-and-figures.pdf. Accessed November 2016.

² Alzheimer's Disease International. Dementia statistics. <http://www.alz.co.uk/research/statistics>. Accessed November 2016.

Media - Nicole Hebert; hebert_nicole@lilly.com; 317.701.9984

Investors - Phil Johnson; johnson_philip_l@lilly.com; 317.655.6874



Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lilly-announces-top-line-results->

[of-solanezumab-phase-3-clinical-trial-300367976.html](https://www.fda.gov/oc/ohrt/2017/07/2017-07-20-01-of-solanezumab-phase-3-clinical-trial-300367976.html)

SOURCE Eli Lilly and Company

News Provided by Acquire Media