

Eli Lilly and Company Announces Top-Line Results on Solanezumab Phase 3 Clinical Trials in Patients with Alzheimer's Disease

INDIANAPOLIS, Aug. 24, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the primary endpoints, both cognitive and functional, were not met in either of the two Phase 3, double-blind, placebo-controlled solanezumab EXPEDITION trials in patients with mild-to-moderate Alzheimer's disease. However, a pre-specified secondary analysis of pooled data across both trials showed statistically significant slowing of cognitive decline in the overall study population of patients with mild-to-moderate Alzheimer's disease. In addition, pre-specified secondary subgroup analyses of pooled data across both studies showed a statistically significant slowing of cognitive decline in patients with mild Alzheimer's disease, but not in patients with moderate Alzheimer's disease.

Adverse events with an incidence of at least 1 percent that occurred statistically significantly more in the solanezumab group than in the placebo group were lethargy, rash and malaise (in EXPEDITION1) and angina (in EXPEDITION2).

An ongoing, open-label extension study, EXPEDITION-EXT, is fully enrolled and will continue as planned.

"We recognize that the solanezumab studies did not meet their primary endpoints, but we are encouraged by the pooled data that appear to show a slowing of cognitive decline," said John C. Lechleiter, Ph.D., chairman, president and chief executive officer, Lilly. "We intend to

discuss these data with regulatory authorities to gain their insights on potential next steps."

"Lilly is committed to finding medicines that alter the underlying pathology of Alzheimer's disease for the benefit of patients and their loved ones," said Jan Lundberg, Ph.D., executive vice president, science and technology, and president, Lilly Research Laboratories. "We believe the pooled data support the amyloid hypothesis, as these are the first Phase 3 data with an anti-beta amyloid agent that appear to show a slowing of cognitive decline."

An independent analysis of the data from the EXPEDITION studies is being performed by the Alzheimer's Disease Cooperative Study (ADCS), an academic national research consortium that facilitates the discovery, development and testing of new drugs for the treatment of Alzheimer's disease. ADCS will present their findings at the American Neurological Association (ANA) meeting in Boston, Mass., on October 8, 2012, and at the Clinical Trials on Alzheimer's Disease (CTAD) meeting in Monte Carlo, Monaco, on October 30, 2012.

The next steps for solanezumab have not yet been decided and will be determined after discussions with regulators.

About the clinical trial endpoints for the EXPEDITION studies

The EXPEDITION1 study did not meet co-primary cognitive and functional endpoints in the overall mild-to-moderate patient population; however, pre-specified

secondary^Â subgroup analyses in patients with mild Alzheimer's disease showed a statistically significant reduction in cognitive decline. Based on those results, Lilly modified the statistical analysis plan (SAP) for EXPEDITION2 prior to database lock to specify a single primary endpoint of cognition in the mild patient population. This revised primary endpoint did not achieve statistical significance. In both of the EXPEDITION study protocols, mild Alzheimer's disease was defined as a baseline Mini-Mental Status Examination (MMSE) score of 20 to 26 and moderate Alzheimer's disease was defined as a baseline MMSE score of 16 to 19.

About solanezumab and the EXPEDITION studies

Solanezumab is a monoclonal antibody being studied as a potential therapy for Alzheimer's disease.

The two, Phase 3 double-blind, placebo-controlled solanezumab EXPEDITION clinical trials included more than 2,050 patients with mild-to-moderate Alzheimer's disease in 16 countries around the world. The trials were 18-months in duration.

About Alzheimer's disease

Alzheimer's disease, the most common form of dementia, causes progressive decline in memory and other aspects of cognition.(1),(2) Researchers do not know exactly what causes Alzheimer's disease and there are currently no approved treatments shown to slow the progression of this devastating disease, only treatment options that reduce certain symptoms of the disease.(1),(2),(3) Alzheimer's Disease International (ADI) estimates that

there are currently 35.6 million people with dementia worldwide, with 7.7 million new cases each year (which implies one new case every four seconds).(4) The number of people affected is estimated to be over 115 million by 2050.(4) Estimates vary, but experts suggest that as many as 5.4 million Americans may have Alzheimer's disease.(2)

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers through medicines and information for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com. P-LLY

This press release contains certain forward-looking statements about solanezumab. This release reflects Lilly's current beliefs; however, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date, or that solanezumab will be approved as a product or will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

- (1) National Institute of Neurological Disorders and Stroke. "Dementia: Hope Through Research." Available at: http://www.ninds.nih.gov/disorders/dementias/detail_dementia.htm#1908919213. Accessed on August 13, 2012.
- (2) Alzheimer's Association. "2012 Alzheimer's Disease Facts and Figures." Available at: http://www.alz.org/downloads/facts_figures_2012.pdf. Accessed on August 13, 2012.
- (3) Perrin, R., et al. "Multimodal techniques for diagnosis and prognosis of Alzheimer's disease." *Nature* 2009 (461); 916-922.
- (4) Alzheimer's Disease International. "Dementia Statistics." Available at: <http://www.alz.co.uk/research/statistics>. Accessed on August 13, 2012.

SOURCE Eli Lilly and Company
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