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Lilly Voluntarily Terminates Phase II Study for LY2886721, a Beta Secretase Inhibitor, Being Investigated as a Treatment for Alzheimer's Disease

Decision does not impact other Lilly Alzheimer's compounds in development

INDIANAPOLIS, June 13, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced it has stopped its Phase II study (BACC) for LY2886721, a beta secretase (BACE) inhibitor being investigated as a once daily treatment for its potential to slow the progression of Alzheimer's disease. The decision to terminate the study was due to abnormal liver biochemical tests. Clinical study investigators have been notified.

"While stopping this Phase II study for our BACE inhibitor is disappointing, patient safety is of utmost importance to Lilly," said Jan M. Lundberg, Ph.D., executive vice president, science and technology, and president, Lilly Research Laboratories. "Discovering and developing medicines for devastating diseases like Alzheimer's is fraught with many challenges, but Lilly's 25-year commitment to bringing medicines to the millions of Alzheimer's disease patients who are waiting will not wane."

The cases of abnormal liver biochemical tests were identified as part of routine monitoring. Lilly will continue to monitor all participants with abnormal liver biochemical tests.

Based on the information Lilly has today, it believes that the abnormal liver biochemical tests observed in this study are not related to the BACE mechanism and continues to be interested in developing BACE inhibitors for the benefit of patients with Alzheimer's disease. Lilly will further evaluate this data prior to determining next steps for the entire LY2886721 clinical development program.

The company expects to incur a financial charge associated with the decision to stop this trial. However, the amount of this charge is not expected to be material and is not expected to result in a change to the company's previously-issued 2013 financial guidance.

About Alzheimer's disease

The total number of new cases of dementia each year worldwide is nearly 7.7 million, which is the equivalent of one new case every 4 seconds.¹ According to different estimates, between 2 and 10 percent of all cases of dementia start before the age of 65. Advancing age is the strongest risk factor for Alzheimer's disease, with age-specific prevalence nearly doubling every 5 years beyond the age of 65.¹ The total estimated worldwide cost of dementia was \$604 billion in 2010.¹

About Lilly's Neuroscience Pipeline

Lilly currently has eight potential new medicines in its clinical development pipeline being evaluated to treat neuroscience-related diseases and disorders, including: schizophrenia, Alzheimer's disease, depression, bipolar disorder, migraine prevention and osteoarthritis pain. Of the eight potential new medicines, two are currently in Phase III clinical development — edivoxetine and solanezumab.

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.

This press release contains certain forward-looking statements about LY2886721, a beta secretase (BACE) inhibitor being investigated as a potential treatment for Alzheimer's disease, and 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 the study findings to date, that this or other BACE inhibitors that might be developed by Lilly in the future will receive regulatory approval or, if approved, would 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.

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[i] Alzheimer's Disease International and World Health Organization 2012 report: Dementia: a public health priority. Available at: http://www.who.int/mental_health/publications/dementia_report_2012. Accessed on August 11, 2012.

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