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Eli Lilly and Company and AstraZeneca Initiate Pivotal Clinical Trial for Patients with Early Alzheimer's Disease

Phase II/III trial of AZD3293, an oral potent small molecule inhibitor of BACE, aims to enroll more than 1,500 patients in 15 countries

INDIANAPOLIS, Dec. 1, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and AstraZeneca today announced enrollment of the first patient into AMARANTH, a Phase II/III study of an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for Alzheimer's disease.

AZD3293, also known as LY3314814, has been shown in Phase I studies to reduce levels of amyloid-beta in the cerebro-spinal fluid of Alzheimer's patients and healthy volunteers. The progression of Alzheimer's disease is characterized by the accumulation of amyloid plaque in the brain. BACE is an enzyme associated with the development of beta-amyloid. Inhibiting BACE is expected to prevent the formation of amyloid plaque and eventually slow the progression of the disease.

The pivotal study will investigate the safety and efficacy of AZD3293/ LY3314814 compared with placebo in the treatment of early Alzheimer's disease.

"We're excited to take this important next step in Lilly's continuing efforts to make life better for so many people and families affected by Alzheimer's disease," said Phyllis Ferrell, global brand development leader for Alzheimer's disease at Lilly. "Our AstraZeneca partners share our determination to find answers for this condition that shatters lives. We're pleased that the first patient enrollment in AMARANTH comes fewer than three months since we announced our alliance."

Samantha Budd, Vice President and Head of Translational Science in AstraZeneca's Neuroscience Innovative Medicines Unit said: "There is a critical need for the development of new medicines that can change the course of Alzheimer's disease. We believe that BACE inhibitors have the potential to target one of the key drivers of this devastating disease. Together with Lilly, we have unique expertise that will allow us to evaluate the potential of AZD3293 as a treatment for Alzheimer's patients."

AstraZeneca and Lilly announced an alliance earlier in 2014 for the development and commercialization of AZD3293/ LY3314814. Under the agreement, Lilly will lead clinical development, working with researchers from AstraZeneca's Neuroscience Innovative Medicines Unit, while AstraZeneca will be responsible for manufacturing. The companies will take joint responsibility for commercialization of the molecule and will share all future costs equally for development and commercialization, as well as net global revenues post-launch.

About the AMARANTH study

AMARANTH is a Phase II/III study that will further investigate the safety and efficacy of AZD3293/LY3314814 and test the hypothesis that it is a disease-modifying treatment for patients with early Alzheimer's disease. Early Alzheimer's disease is defined as the continuum of patients with mild cognitive impairment (MCI) due to Alzheimer's disease and patients diagnosed with mild Alzheimer's dementia. The study, which has a two-year treatment period, aims to enroll more than 1500 patients in 15 countries.

About Alzheimer's disease

Alzheimer's disease, a fatal illness, is the most common form of dementia, accounting for 60 to 80 percent of dementia cases. [1] It continues to be one of the most significant health challenges facing the United States, with an estimated 5 million Americans over age 65 suffering from the disease. [1] In the absence of significant change, Alzheimer's disease will cripple not only the families of aging baby boomers, but also the healthcare systems of many developed nations. The U.S. spends approximately \$203 billion a year in direct expenses associated with Alzheimer's disease, and that number will grow to over \$1 trillion by 2050[1] if something is not done to affect the progression of the disease and delay the debilitating associated dementia.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

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 <http://newsroom.lilly.com/social-channels>.

This press release contains forward-looking statements about LY3314814/AZD3293 as a potential treatment for Alzheimer's disease and reflects Lilly's current belief. 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, 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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[1] Alzheimer's Association. 2013 Alzheimer's disease facts and figures. *Alzheimers Dement.* 2013;9(2):208-245.

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The Lilly logo is rendered in a vibrant red, cursive script. The letters are fluid and interconnected, with a classic, elegant feel. The 'L' is particularly large and prominent, leading into the 'i', 'l', 'l', 'y' which follow in a similar flowing style. The overall appearance is that of a handwritten signature or a stylized brand mark.

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

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/eli-lilly-and-company-and-astrazeneca-initiate-pivotal-clinical-trial-for-patients-with-early-alzheimers-disease-300002343.html>

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