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Eli Lilly and Company and AstraZeneca Announce Continuation of Pivotal Clinical Trial for People with Early Alzheimer's Disease

Phase 2/3 trial of AZD3293, an oral potent small molecule BACE inhibitor, will continue to Phase 3 after positive interim safety data

INDIANAPOLIS, April 8, 2016 /CNW/ -- Eli Lilly and Company (NYSE: LLY) and AstraZeneca today announced that AMARANTH, a Phase 2/3 study of AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for early Alzheimer's disease, will continue to Phase 3 of the Phase 2/3 seamless trial.

The AMARANTH independent data monitoring committee recommended the study continue without modification after a scheduled interim safety analysis was conducted. The analysis was not designed to review efficacy.

"This is an important and meaningful step forward on the path to better understand the Alzheimer's puzzle," said Phyllis Ferrell, vice president and global development leader for Alzheimer's disease at Lilly. "We'd like to thank the AMARANTH participants and the trial investigators for taking part in this important study, and thank our colleagues at AstraZeneca for their partnership."

AZD3293 has been shown in Phase 1 studies to reduce levels of amyloid beta in the cerebro-spinal fluid of people with Alzheimer's 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 amyloid beta. Inhibiting BACE is expected to prevent the formation of amyloid plaque and eventually slow the progression of the disease.

"Alzheimer's disease remains one of the biggest challenges facing medical science today. BACE inhibitors have the potential to target one of the key drivers of disease progression and we are delighted that our combined efforts have resulted in the development of AZD3293 moving into the next phase of study," said Menelas Pangalos, executive vice president, IMED Biotech Unit, AstraZeneca. "Disease-modifying approaches, such as this, have the potential to transform the treatment of Alzheimer's disease and help patients in this area of large unmet medical need."

Under the terms of the agreement, AstraZeneca will receive a milestone payment from Lilly now that AZD3293 has moved into Phase 3 testing. The payment will result in a second-quarter charge of $100 million (pre-tax) to Lilly's GAAP and non-GAAP research and development expense.

Lilly and AstraZeneca have also announced the planned initiation of a new Phase 3 trial for AZD3293. The trial, named DAYBREAK, will study the safety and efficacy of AZD3293 in people with mild Alzheimer's dementia. DAYBREAK will begin enrolling participants in the third quarter of 2016.

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

About the AMARANTH study
AMARANTH is a Phase 2/3 study that is investigating the safety and efficacy of AZD3293 and testing 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 approximately 2,200 patients in 14 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] There are currently an estimated 46 million people living with dementia worldwide, and this number is expected to

grow to more than 74 million in 2030 and 131 million in 2050.[2] Only 50 percent of people with dementia ever receive a formal diagnosis,[3] and Alzheimer's disease continues to be one of the most significant health challenges facing the world. The total estimated worldwide cost of dementia in 2015 was $818 billion.[2] By 2018, dementia will become a trillion dollar disease, rising to $2 trillion by 2030. [2]

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 diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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 newsroom.lilly.com/social-channels.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) 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. Among other things, there can be no guarantee that LY3314814/AZD3293 will receive regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, 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.

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[1] Alzheimer's Association. 2016 Alzheimer's Disease Facts and Figures. *Alzheimer's & Dementia.* 2016; 12(4).

[2] Prince M, et al. World Alzheimer Report 2015: The Global Impact of Dementia, An Analysis of Prevalence, Incidence, Cost and Trends. *Alzheimer's Disease International.* August 2015.

[3] Department of Health. Dementia - a state of the nation report on dementia care and support in England. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/262139/Dementia.pdf. Accessed 8 July 2015.

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