



August 22, 2016

Lilly and AstraZeneca Receive FDA Fast Track Designation for AZD3293, an Investigational Treatment for Early Alzheimer's Disease

AZD3293 is an oral potent small molecule BACE inhibitor in phase 3 development

INDIANAPOLIS, Aug. 22, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and AstraZeneca today announced they have received U.S. Food and Drug Administration (FDA) Fast Track designation for the development program in Alzheimer's disease for AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in phase 3 clinical trials. The FDA's Fast Track program is designed to expedite the development and review of new therapies to treat serious conditions and tackle key unmet medical needs.

"We are pleased the FDA places a high priority on the development of drugs that target Alzheimer's disease, one of the most critical health issues of our time," said Phyllis Ferrell, vice president and global development leader for Alzheimer's disease at Lilly. "Most importantly, this is a positive step forward for the millions of patients, families, caregivers, advocates and healthcare providers who fight every day for progress."

"The Fast Track designation in the U.S. for this promising potential therapy reinforces the ambition of the AstraZeneca-Lilly BACE alliance to help advance science for patients and their families managing this devastating illness," said Craig Shering, AZD3293 Project Lead in Global Medicines Development at AstraZeneca. "BACE inhibitors have the potential to transform the treatment of Alzheimer's disease, one of the biggest challenges facing medical science today."

In addition to the continuing AMARANTH phase 2/3 study, Lilly and AstraZeneca have also announced the planned initiation of a second phase 3 trial for AZD3293. The trial, called DAYBREAK-ALZ, studies the safety and efficacy of AZD3293 in people with mild Alzheimer's dementia and began enrolling participants in the third quarter of 2016.

AZD3293 has been shown in 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 and build-up of amyloid plaque which in turn may help slow the progression of the disease.

About the AstraZeneca and Lilly BACE Alliance

AstraZeneca and Lilly announced an alliance in 2014 for the development and commercialization of AZD3293. Under the agreement, Lilly will lead clinical development, working with researchers from AstraZeneca's Research and Development Team, 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 Alzheimer's disease

Alzheimer's disease is a fatal illness and is the most common form of dementia, accounting for 60 to 80 percent of cases.¹ There are currently an estimated 46 million people living with dementia worldwide, and this number is expected to exceed 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, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Respiratory and Autoimmunity, Cardiovascular and Metabolic Diseases, and Oncology. The company is also active in inflammation, infection

and neuroscience through numerous collaborations. 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.

P-LLY

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.



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

Refer to:

Media: Nicole Hebert, nicole_hebert@lilly.com, +1-317-701-9984

Investors: Phil Johnson, johnson_philip_l@lilly.com, +1-317-655-6874

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lilly-and-astrazeneca-receive-fda-fast-track-designation-for-azd3293-an-investigational-treatment-for-early-alzheimers-disease-300315784.html>

SOURCE Eli Lilly and Company

News Provided by Acquire Media