ASTRAZENECA PLC
Form 6-K
April 08, 2016

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of April 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

ASTRAZENECA AND ELI LILLY AND COMPANY ANNOUNCE CONTINUATION OF PIVOTAL CLINICAL TRIAL FOR PEOPLE WITH EARLY ALZHEIMER'S DISEASE

Phase II/III trial of AZD3293, an oral potent small molecule BACE inhibitor,

will continue to Phase III after positive interim safety data

AstraZeneca and Eli Lilly and Company today announced that AMARANTH, a Phase II/III 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 into Phase III of the Phase II/III 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.

Menelas Pangalos, Executive Vice President, IMED Biotech Unit, AstraZeneca, said: "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. 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."

AZD3293 has been shown in Phase I studies to reduce levels of amyloid beta in the cerebro-spinal fluid of people with Alzheimer's disease and healthy volunteers. The progression of Alzheimer's disease is characterised 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.

Phyllis Ferrell, vice president and global development leader for Alzheimer's disease at Lilly said: "This is an important and meaningful step forward on the path to better understand the Alzheimer's puzzle. 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."

AstraZeneca and Lilly have also announced the planned initiation of a new Phase III 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.

Financial Considerations

Under the terms of the agreement, AstraZeneca will receive a further milestone payment from Lilly now that AZD3293 will move into Phase III testing. The payment of $100 million will be reported as Externalisation Revenue in AstraZeneca's financial statements and does not change the financial guidance for 2016.

About the AMARANTH study

AMARANTH is a Phase II/III 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 more than 2200 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. 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. Only 50 percent of people with dementia ever receive a formal diagnosis, 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. By 2018, dementia will become a trillion dollar disease, rising to $2 trillion by 2030.

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.

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

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Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

08 April 2016

-ENDS-

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 08 April 2016

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary