ASTRAZENECA PLC
Form 6-K
June 12, 2018

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 June 2018

Commission File Number: 001-11960

AstraZeneca PLC

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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 PLC

INDEX TO EXHIBITS

1.
Update: lanabecestat Phase III Alzheimer's trials

This announcement contains inside information

12 June 2018 07:00 BST

Update on Phase III clinical trials of lanabecestat for Alzheimer's disease

Independent data monitoring committee advises lanabecestat is unlikely to meet primary endpoints, leading to decision to discontinue these trials

AstraZeneca and Eli Lilly and Company (Lilly) are discontinuing the global Phase III clinical trials of lanabecestat, an oral beta secretase cleaving enzyme (BACE) inhibitor, for the treatment of Alzheimer's disease. The decision is based on recommendations by an independent data monitoring committee (IDMC), which concluded that both the AMARANTH trial, in early Alzheimer's disease, and the DAYBREAK-ALZ trial, in mild Alzheimer's disease dementia, were not likely to meet their primary endpoints upon completion and therefore should be stopped for futility. As a result of this decision, the related AMARANTH extension trial will also be discontinued.

Menelas Pangalos, Ph.D., Executive Vice President, IMED Biotech Unit, AstraZeneca, said: "We are saddened by this outcome as our researchers are working tirelessly to find a solution for the many people who are impacted by this devastating disease. We are committed to ensuring our findings can be used to inform further research in the Alzheimer's community, given the importance of finding a treatment for this disease."

The IDMC recommendation to stop the studies was not based on safety concerns. The AstraZeneca and Lilly BACE alliance for lanabecestat remains in place and the companies will now work with the clinical trial sites involved to implement the discontinuations.

"The complexity of Alzheimer's disease poses one of the most difficult medical challenges of our time, and we are deeply disappointed for the millions suffering from this devastating disease," said Daniel Skovronsky, M.D., Ph.D., president of Lilly Research Labs. "We are grateful for the contributions of the study participants and their families and encourage them to consider other Alzheimer's disease clinical trials. Lilly remains dedicated to Alzheimer's disease research as we have been for the last three decades. We won't give up on finding a solution for Alzheimer's patients."

The AMARANTH trial randomised patients with early Alzheimer's disease to receive lanabecestat, 20mg or 50mg, or placebo orally once daily for 104 weeks. The primary endpoint of the trial was change from baseline on the 13-item Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog13). Early Alzheimer's disease is defined as the continuum of patients with mild cognitive impairment due to Alzheimer's disease and patients diagnosed with mild Alzheimer's disease dementia. Patients who completed the AMARANTH trial were given the opportunity to enrol in the AMARANTH extension trial, where all patients received active treatment.

The DAYBREAK-ALZ trial randomised patients with mild Alzheimer's disease dementia to receive either lanabecestat, 20mg or 50mg, or placebo orally once daily for 156 weeks. The primary endpoint of the trial was change from baseline on ADAS-Cog13.

Financial considerations

The discontinuation of the lanabecestat Phase III clinical trials in Alzheimer's disease is not expected to have a material impact on the Company's financial guidance for 2018, which therefore remains unchanged.

About Alzheimer's disease

Alzheimer's disease is a fatal illness that causes progressive decline in memory and other aspects of cognition.1 Dementia due to Alzheimer's disease is the most common form of dementia, accounting for 60 to 80 percent of all cases.2 There are currently an estimated 50 million people living with dementia around the world, with numbers expected to increase to nearly 75 million by 2030 and 132 million by 2050. Almost 10 million new cases of dementia are diagnosed each year worldwide, implying one new case approximately every three seconds.3 The current total annual societal and economic estimated cost of dementia is $818 billion USD worldwide and this year may rise above a trillion USD.3

About the AstraZeneca and Lilly BACE Alliance

AstraZeneca and Lilly announced an alliance in 2014 for the development and commercialisation of lanabecestat. It was agreed that Lilly would lead clinical development, working with researchers from AstraZeneca's Research and Development Team, while AstraZeneca would be responsible for manufacturing.

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 www.lilly.com/newsroom/social-channels.

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 - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. 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 and follow us on Twitter @AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

References

1 Alzheimer's Association. What is Alzheimer's? http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp. Accessed April 2018.
2 Alzheimer's Association. What is Dementia? http://www.alz.org/what-is-dementia.asp. Accessed April 2018.
3 Alzheimer's Disease International. Dementia Statistics. https://www.alz.co.uk/research/statistics. Accessed April 2018.

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: 12 June 2018

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