

ASTRAZENECA PLC
Form 6-K
October 04, 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 October 2016

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 ☒ 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):

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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 ☒

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. AstraZeneca reports top-line EUCLID results in PAD dated 04th October 2016

This announcement contains inside information

04 October 2016 07:00

ASTRAZENECA REPORTS TOP-LINE RESULTS FROM THE BRILINTA EUCLID TRIAL IN PATIENTS WITH PERIPHERAL ARTERY DISEASE

Brilinta did not demonstrate a benefit over clopidogrel in a symptomatic peripheral artery disease patient population

AstraZeneca today announced top-line results from the EUCLID trial. Brilinta (ticagrelor) did not demonstrate a benefit over clopidogrel in a symptomatic peripheral artery disease (PAD) patient population and therefore did not meet the primary endpoint of the trial.

The EUCLID trial included 13,885 patients in 28 countries and is the largest cardiovascular (CV) outcomes trial to date conducted exclusively in symptomatic patients with PAD. It evaluated the treatment of Brilinta 90mg tablets twice daily versus clopidogrel 75mg once daily for the prevention of atherothrombotic events (a composite of cardiovascular death, heart attack or ischaemic stroke). The primary endpoint of the trial was the time to first occurrence of any such event.

Based on preliminary analyses, safety data is consistent with the known safety profile of Brilinta.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The proven benefits of Brilinta in acute coronary syndrome and post-myocardial infarction patients are established and remain unchanged. We are disappointed that the EUCLID trial results showed Brilinta did not demonstrate a benefit over clopidogrel in this specific symptomatic PAD population."

Full results from the EUCLID trial are expected to be presented at the American Heart Association Scientific Sessions in New Orleans, Louisiana in November 2016.

About Peripheral Artery Disease (PAD)

PAD is the third most common cause of cardiovascular complications (largely myocardial infarction and stroke) in the world. PAD is a chronic and progressive clinical manifestation of a systemic atherosclerotic vascular disease and a predictor of future vascular events. However, only a limited number of PAD patients receive the recommended treatment advocated in international guidelines. There is no cure and patients endure a high risk of serious cardiovascular morbidity and mortality.

About EUCLID

EUCLID (Examining Use of tiCagrelor In paD) is a global, event-driven, double-blind, parallel group trial involving approximately 13,800 patients in 28 countries, and was run for AstraZeneca by The Duke Clinical Research Institute (DCRI), part of the Duke University School of Medicine, Durham, North Carolina. The EUCLID trial evaluated the efficacy and safety of long-term treatment with Brilinta 90mg twice daily compared to clopidogrel 75mg once daily for the prevention of atherothrombotic events (a composite of ischaemic stroke, myocardial infarction and CV death)

in patients ≥ 50 years of age with symptomatic PAD, defined by ankle-brachial index (ABI) ≤ 0.80 (at enrolment) and lower extremity symptoms, or by prior lower extremity revascularisation more than 30 days prior.

About the PARTHENON programme

PARTHENON is the largest-ever AstraZeneca CV outcomes programme, involving nearly 85,000 patients at high risk of CV events (MI, stroke and/or CV death) due to their underlying disease. Through the PARTHENON programme, AstraZeneca aims to address unmet patient needs by enhancing scientific understanding of the potential role of Brilinta in the treatment of atherothrombotic conditions. It includes five key trials covering broad patient populations across varying timescales. The trials encompass a wide range of CV disorders, including coronary artery disease (PEGASUS-TIMI 54), acute coronary syndrome (PLATO), stroke (SOCRATES) and patients with type 2 diabetes at high risk of CV events (THEMIS).

About Brilinta

Brilinta is a direct-acting P2Y₁₂ receptor antagonist in a chemical class called cyclo-pentyl-triazolo-pyrimidines (CPTPs). Brilinta works by inhibiting platelet activation and has been shown to reduce the rate of atherothrombotic CV events, such as heart attack or CV death, in patients with acute coronary syndrome (ACS).

Brilinta 90mg is indicated to reduce the rate of atherothrombotic CV events in patients with ACS [unstable angina (UA), non-ST-elevation myocardial infarction (NSTEMI), or ST-elevation myocardial infarction (STEMI)]. Brilinta 60mg is indicated for the treatment of patients who have suffered a heart attack at least one year prior and are at high risk of developing a further atherothrombotic event. Treatment with Brilinta 60mg may be started as continuation therapy after an initial one-year treatment with Brilinta 90mg and aspirin or other dual anti-platelet therapy. Brilinta has been shown to reduce the rate of a combined end point of CV death, MI, or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with percutaneous coronary intervention, it also reduces the rate of stent thrombosis.

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, Cardiovascular & Metabolic Diseases, and Oncology. The Company is also selectively active in Neuroscience and Autoimmunity. 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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Adrian Kemp
Company Secretary
AstraZeneca PLC

-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: 04 October 2016 By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary