

ASTRAZENECA PLC
Form 6-K
January 14, 2015

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 January 2015

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 ☒ 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 ☒

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

PEGASUS-TIMI 54 STUDY OF BRILINTA® MEETS
PRIMARY ENDPOINT IN BOTH 60MG AND 90MG DOSES

Both BRILINTA 60mg and 90mg demonstrate statistically significant reduction in major cardiovascular thrombotic events in patients with a history of heart attack

AstraZeneca today announced that the PEGASUS-TIMI 54 study, a large scale outcomes trial involving over 21,000 patients, successfully met its primary efficacy endpoint. The study assessed BRILINTA® (ticagrelor) tablets at either 60mg twice daily or 90mg twice daily plus low-dose aspirin for the secondary prevention of atherothrombotic events in patients who had experienced a heart attack one to three years prior to study start. The primary efficacy endpoint was a composite of cardiovascular (CV) death, myocardial infarction (MI) or stroke.

Preliminary analysis did not reveal any unexpected safety issues. Full evaluation of the data is ongoing.

Elisabeth Björk, Vice President, Head of Cardiovascular and Metabolic Diseases, Global Medicines Development, AstraZeneca, said: "We are very pleased with the top line results of the PEGASUS-TIMI 54 study, the second positive major outcomes study in the PARTHENON programme. The results build on existing understanding of the benefits of BRILINTA for patients with acute coronary syndrome and offer important clinical insights into its potential role for the longer term prevention of cardiovascular events. We look forward to presenting the data later this year."

The PEGASUS-TIMI 54 study investigated two different doses of ticagrelor on a background of low dose aspirin versus placebo plus low dose aspirin, in patients aged 50 and older with a history of heart attack and one additional CV risk factor¹. The study was designed to better understand the management of patients more than 12 months after their heart attack, who remain at high risk for major thrombotic events.

Complete results from the PEGASUS-TIMI 54 study will be submitted to a scientific meeting in 2015 and pending further analysis, AstraZeneca plans to file this data with regulatory health authorities. Ticagrelor is not approved for secondary prevention of atherothrombotic events in patients with a history of heart attack beyond one year.

The PEGASUS-TIMI 54 study is part of AstraZeneca's PARTHENON programme. The PLATO study, involving over 18,000 patients, was the first study in the programme and is the basis on which ticagrelor has been approved in over 100 countries and included in 12 major ACS treatment guidelines globally. Further ongoing PARTHENON studies are assessing ticagrelor for the prevention of cardiovascular events in patients with peripheral arterial disease, ischaemic stroke or transient ischaemic attack, and in patients with diabetes and coronary atherosclerosis.

¹ Bonaca MP, Bhatt DL, Braunwald E, et al. Design and rationale for the Prevention of Cardiovascular Events in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin-Thrombolysis in Myocardial Infarction 54 (PEGASUS-TIMI 54) trial. Am Heart J. 2014;167:437-44.

About PEGASUS-TIMI 54

PEGASUS-TIMI 54 (PrEvention with TicaGrelor of SecondAry Thrombotic Events in High-RiSk Patients with Prior AcUte Coronary Syndrome - Thrombolysis In Myocardial Infarction Study Group) is one of AstraZeneca's largest ever outcomes trials with more than 21,000 patients from over 1,100 sites in 31 countries in Europe, the Americas, Africa and Australia/Asia. It was conducted in collaboration with the Thrombolysis in Myocardial Infarction (TIMI) Study Group from Brigham and Women's Hospital (Boston, MA, USA).

About the PARTHENON programme

The PEGASUS study is part of PARTHENON, the largest ever AstraZeneca cardiovascular outcomes programme, involving nearly 80,000 patients at high risk of cardiovascular events (MI, stroke and/or cardiovascular death) due to their underlying disease. PARTHENON aims to enhance scientific understanding of the role of ticagrelor in the treatment of atherothrombotic conditions. It includes five key studies covering broad patient populations across varying timescales. The studies encompass a wide range of cardiovascular disorders, including stroke/transient

ischaemic attack (SOCRATES), peripheral arterial disease (EUCLID) and patients with type 2 diabetes at high risk of cardiovascular events (THEMIS).

The PARTHENON programme aims to support four new indications for ticagrelor over the next 4 years.

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 thrombotic CV events, such as a heart attack or CV death, in patients with acute coronary syndrome (ACS).

BRILINTA (90mg) is indicated to reduce the rate of thrombotic CV events in patients with ACS (unstable angina [UA], non-ST-elevation myocardial infarction [NSTEMI], or ST-elevation myocardial infarction [STEMI]). 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.

BRILINTA is a registered trademark of the AstraZeneca group.

About the Thrombolysis in Myocardial Infarction (TIMI) Study Group

The TIMI Study Group is affiliated with Brigham and Women's Hospital and Harvard Medical School and is located in Boston, Massachusetts. It is one of the oldest cardiovascular academic research organisation in the United States and has conducted numerous practice-changing clinical trials in patients with CV disease or risk factors for CV disease.

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 cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. 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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14 January 2015

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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: 14 January 2015

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