ASTRAZENECA PLC
Form 6-K
March 16, 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 March 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 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-_____

PEGASUS-TIMI 54 STUDY SHOWS THAT LONG-TERM TREATMENT WITH BRILINTA REDUCED THROMBOTIC CARDIOVASCULAR EVENTS IN PATIENTS WITH A HISTORY OF HEART ATTACK

Data from 21,000 patient study presented at American College of Cardiology 64th Annual Scientific Session and simultaneously published in New England Journal of Medicine

AstraZeneca on Saturday announced full results from the PEGASUS-TIMI 54 study, a large-scale outcomes trial that investigated BRILINTA® (ticagrelor) tablets plus low dose aspirin, compared to placebo plus low dose aspirin, for the chronic secondary prevention of atherothrombotic events in patients who had experienced a heart attack one to three years prior to study enrolment.

Key findings:

- Both 90mg and 60mg study doses of ticagrelor with aspirin significantly reduced the primary composite endpoint of cardiovascular (CV) death, myocardial infarction (MI) or stroke compared to placebo.
- As expected with an oral antiplatelet and consistent with studies in similar patient populations, TIMI Major Bleeding1, the study's primary safety endpoint, was higher with both doses of ticagrelor plus aspirin compared to placebo plus aspirin. Importantly, the rates of intracranial haemorrhage (bleeding within the skull) and fatal bleeding were low and were similar between study groups and the placebo arm.

The data were presented during the opening late-breaking clinical trial session of the American College of Cardiology's 64th Annual Scientific Session and Expo, and also simultaneously published in the New England Journal of Medicine online.

Elisabeth Björk, Vice President, Head of Cardiovascular and Metabolic Diseases, Global Medicines Development, AstraZeneca, said: "As a company we are committed to furthering cardiovascular research and are proud to have delivered the PEGASUS-TIMI 54 study, AstraZeneca's largest clinical trial, involving more than 21,000 patients worldwide. Building on the landmark PLATO trial in acute coronary syndrome, the positive PEGASUS study adds to the body of evidence for BRILINTA and is the first prospective trial to evaluate longer term dual antiplatelet therapy in higher risk patients with a history of a heart attack."

"We have just submitted regulatory filings to the European Medicines Agency and the US Food and Drug Administration and we look forward to working with these agencies towards a potential new indication in major markets."

Recent research has shown that one in five patients will have a further heart attack, stroke or CV death in the subsequent three years following a heart attack, even if patients were event free after 12 months2. For patients more than one year on from a heart attack, the current standard of care is aspirin alone. The PEGASUS-TIMI 54 study was designed to investigate the effect of adding ticagrelor at 60mg and 90mg to low dose aspirin on reducing the risk of CV death, heart attack or stroke in patients aged 50 and older with a history of heart attack and one additional CV risk factor.

Efficacy Findings

In this trial, both study doses of ticagrelor significantly reduced the primary endpoint of CV death, MI or stroke compared to placebo. The rates at 3 years were 7.85% in the ticagrelor 90mg arm, 7.77% in the ticagrelor 60mg arm, and 9.04% in the placebo arm (Hazard Ratio (HR) for ticagrelor 90mg vs placebo 0.85, 95% CI 0.75 - 0.96, P=0.0080; HR for ticagrelor 60mg vs placebo 0.84, 95% CI 0.74 - 0.95, P=0.0043).

The effect of ticagrelor on each of the components of the primary endpoint was consistent. A numerical decrease in the secondary endpoints of cardiovascular death and all cause mortality was observed, but did not reach statistical significance.

In addition, the primary efficacy endpoint of both doses of ticagrelor appeared consistent across major subgroups including age, sex, index MI type (STEMI/NSTEMI), time from qualifying MI, diabetes, aspirin dose, history of percutaneous intervention (angioplasty), and geographical region.

Safety Findings

As expected, TIMI Major bleeding was higher with both doses of ticagrelor compared to placebo, with rates at 3 years of 2.60% in the ticagrelor 90mg arm, 2.30% in the ticagrelor 60mg arm, and 1.06% in the placebo arm (HR for ticagrelor 90mg vs placebo 2.69, 95% CI 1.96 - 3.70, p<0.001; HR for ticagrelor 60mg vs placebo 2.32, 95% CI 1.68 - 3.21, p<0.001).

However, the rates of fatal bleeding or intracranial haemorrhage were low and similar between treatment arms.

Fatal bleeding rates at 3 years were 0.11% in the ticagrelor 90mg arm, 0.25% in the ticagrelor 60mg arm, and 0.26% in the placebo arm (HR for ticagrelor 90mg vs placebo 0.58, 95% CI 0.22 - 1.54, p=0.27; HR for ticagrelor 60mg vs placebo 1.00, 95% CI 0.44 - 2.27, p=1.00).

Intracranial haemorrhage rates at 3 years were 0.56% in the ticagrelor 90mg arm, 0.61% in the ticagrelor 60mg arm, and 0.47% in the placebo arm (HR for ticagrelor 90mg vs placebo 1.44, 95% CI 0.83 - 2.49, p=0.19; HR for ticagrelor 60mg vs placebo 1.33, 95% CI 0.77 - 2.31, p=0.31).

The PEGASUS-TIMI 54 study, AstraZeneca's largest outcomes trials involving more than 21,000 patients from over 1,100 sites in 31 countries, is part of the 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.

BRILINTA is not approved for secondary prevention of atherothrombotic events in patients with a history of heart attack beyond one year or for the prevention of cardiovascular events in patients with peripheral arterial disease, stroke, diabetes or atherosclerosis.

1 TIMI Major Bleeding Classification:

- Any intracranial bleeding, or
- Clinically overt signs of haemorrhage associated with a drop in hemoglobin (Hgb) of ≥5 g/dL (or, when hemoglobin is not available, a fall in hematocrit of ≥15%), or
- Fatal bleeding (a bleeding event that directly led to death within 7 days).

2 Rapsomaniki E, Thuresson M, Yang E, et al. International comparison of outcomes among 140,880 patients stable after acute MI; real world evidence from electronic health and administrative records. Presented at European Society of Cardiology Congress, Barcelona, Spain; 30 August - 3 September 2014.

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 BRILINTA®
BRILINTA is a direct-acting, selective and reversibly binding P2Y12 receptor antagonist in a chemical class called cyclo-pentyl-triazolo-pyrimidines (CPTPs). BRILINTA works by inhibiting platelet activation.

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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16 March 2015

-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: 16 March 2015

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