ASTRAZENECA PLC
Form 6-K
February 19, 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 February 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-_____

BRILIQUE (TICAGRELOR) APPROVED IN EU FOR EXTENDED TREATMENT OF PATIENTS WITH HISTORY OF HEART ATTACK

Approval of new 60mg dose expands current indication to include long-term treatment beyond the first year

AstraZeneca today announced that the European Commission has granted marketing authorisation for Brilique (ticagrelor) at a new 60mg dose 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 may be started as continuation therapy after an initial one-year treatment with Brilique 90mg and aspirin or other dual anti platelet therapy.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "A growing body of evidence continues to show that the risk of experiencing a subsequent cardiovascular event continues beyond the first year after a patient has a heart attack. We are committed to finding new treatment solutions for these patients who remain at risk, and today's approval is an important step forward in meeting this need."

Brilique is an oral antiplatelet treatment that works by inhibiting platelet activation. Brilique 90mg is already approved in the EU for the prevention of atherothrombotic events in adults with acute coronary syndrome (ACS). In the management of ACS, the recommended maintenance dose of Brilique is 90mg twice daily during the first year after an ACS event.

Now, after the first year, patients with a history of heart attack can continue to be treated with the lower dose Brilique 60mg twice daily, which should be taken with a daily maintenance dose of aspirin of 75-150mg.

The EU approval was based on the results from the PEGASUS TIMI-54 study, a large-scale outcomes trial involving more than 21,000 patients, presented at American College of Cardiology Congress (ACC) in March 2015 and simultaneously published in the New England Journal of Medicine. PEGASUS TIMI-54 investigated ticagrelor tablets plus low-dose aspirin, compared to placebo plus low dose aspirin, for the long-term prevention of cardiovascular (CV) death, heart attack and stroke in patients who had experienced a heart attack one to three years prior to study enrollment. The study showed that Brilique significantly reduced the primary endpoint of CV death, MI or stroke compared to placebo. The rates at 3 years were 7.77% in the ticagrelor 60mg arm and 9.04% in the placebo arm.

This approval is applicable to all 28 European Union member countries plus Iceland, Norway and Liechtenstein.

Today's announcement follows the approval on 3 September 2015 of Brilinta (ticagrelor) 60mg by the US Food and Drug Administration, to be used in patients with a history of heart attack beyond the first year.

NOTES TO EDITORS

About BRILIQUE

Brilique is an oral antiplatelet treatment for acute coronary syndrome (ACS). Brilique is a direct-acting P2Y12 receptor antagonist in a chemical class called cyclo-pentyl-triazolo-pyrimidines (CPTPs). Brilique 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 ACS.

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 is being conducted in collaboration with the Thrombolysis in Myocardial Infarction (TIMI) Study Group from Brigham and Women's Hospital (Boston, MA, USA).

The PEGASUS-TIMI 54 study investigated the efficacy and safety of both Brilique 60mg and 90mg, twice daily, compared to placebo on a background of low dose aspirin, for the long-term prevention of atherothrombotic events in patients who suffered a heart attack one to three years prior to enrolment. The primary efficacy endpoint is time to first occurrence of any event from the composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction or non-fatal stroke.

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

19 February 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: 19 February 2016

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