

ASTRAZENECA PLC
Form 6-K
February 25, 2019

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 2019

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):

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- _____

AstraZeneca PLC

INDEX TO EXHIBITS

1. Brilinta's PhIII THEMIS trial met primary endpoint

25 February 2019 07:00 GMT

Brilinta's Phase III THEMIS trial met primary endpoint in patients with established coronary artery disease and type-2 diabetes

Brilinta reduced cardiovascular events in patients with no prior heart attack or stroke

The Phase III THEMIS trial met its primary endpoint and demonstrated that Brilinta (ticagrelor), taken in conjunction with aspirin, showed a statistically-significant reduction in a composite of major adverse cardiovascular events (MACE) compared to aspirin alone.

THEMIS was conducted in over 19,000 patients with coronary artery disease (CAD) and type-2 diabetes (T2D) with no prior heart attack (myocardial infarction, MI) or stroke. Preliminary safety results were consistent with the known profile of Brilinta. A full evaluation of the THEMIS data will be presented at a forthcoming medical meeting.

Elisabeth Björk, Senior Vice President, Head of late Cardiovascular, Renal and Metabolism, R&D BioPharmaceuticals, said: "Approaches to help reduce cardiovascular morbidity further in patients with coronary artery disease and type-2 diabetes are urgently needed. The positive result from the THEMIS trial may offer a potential benefit for this high-risk patient population."

Deepak L. Bhatt, MD, MPH, THEMIS co-Chair and Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital and a Professor at Harvard Medical School said: "The THEMIS trial is the largest randomised trial of patients with type-2 diabetes performed to date and was designed to evaluate whether more-intense antiplatelet therapy is a promising approach. The results could help us refine our understanding of the role of dual antiplatelet therapy in patients across the atherothrombotic spectrum."

Gabriel Steg, MD, THEMIS co-Chair and Professor at Université Paris-Diderot, Paris and Professor at the National Heart and Lung Institute, Imperial College, London said: "Patients who have both stable coronary artery disease and diabetes are a sizeable group which remains at particularly high risk of major adverse cardiac events. The optimal long-term antiplatelet therapy in that group is not fully established. We look forward to presenting the full results from the THEMIS trial later this year."

About THEMIS

THEMIS (Effect of Ticagrelor on Health Outcomes in DiabEtes Mellitus Patients Intervention Study) is an AstraZeneca-sponsored, multi-national, randomised, double-blinded trial in patients with CAD and T2D with no prior myocardial infarction or stroke. THEMIS was designed to test the hypothesis that Brilinta plus aspirin would reduce major adverse cardiovascular events (MACE), a composite of CV death, myocardial infarction or stroke, in patients with CAD and T2D with no prior myocardial infarction or stroke, vs. aspirin alone. CAD was defined as a prior percutaneous coronary intervention (PCI), bypass surgery or at least a 50% narrowing of a coronary artery.

The trial was initiated in early 2014, duration was event-driven across 42 countries and more than 19,000 patients were randomised in order to collect 1,385 independently-adjudicated primary endpoint events.

About Brilinta

Brilinta (ticagrelor) is an oral, reversible, direct-acting P2Y₁₂ receptor antagonist that works by inhibiting platelet activation. Brilinta, together with aspirin, has been shown to significantly reduce the risk of major adverse cardiovascular events (myocardial infarction, stroke or CV death), in patients with acute coronary syndrome (ACS) or a history of MI.

Brilinta, co-administered with aspirin is indicated for the prevention of atherothrombotic events in adult patients with ACS, or for patients with a history of MI and a high risk of developing an atherothrombotic event.

About AstraZeneca in Cardiovascular, Renal & Metabolism (CVRM)

Cardiovascular, renal and metabolism is one of AstraZeneca's main therapy areas and platforms for future growth. By following the science to understand more clearly the underlying links between the heart, kidney and pancreas, AstraZeneca is investing in a portfolio of medicines to protect organs and improve outcomes by slowing disease progression, reducing risks and tackling co-morbidities. Our ambition is to modify or halt the natural course of these diseases and even regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and CVRM health for millions of patients worldwide.

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. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter@AstraZeneca.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

SIGNATURES

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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: 25 February 2019

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary