ASTRAZENECA PLC
Form 6-K
August 19, 2014

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 August 2014

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-_____

UNITED STATES DEPARTMENT OF JUSTICE CLOSES INVESTIGATION INTO PLATO CLINICAL TRIAL FOR BRILINTA

AstraZeneca today announced that it has received confirmation from the United States Department of Justice that it is closing its investigation into PLATO, a clinical trial with Brilinta (ticagrelor). The government is not planning any further action.

Pascal Soriot, Chief Executive Officer, said: "We welcome the Department of Justice's decision not to pursue further action. We have always had absolute confidence in the integrity of the PLATO trial and we are proud of the important benefit Brilinta offers to patients around the world suffering from acute coronary syndrome. As one of AstraZeneca's growth platforms, we are committed to delivering the full potential of this important medicine."

AstraZeneca recently announced the start of the SOCRATES trial, studying Brilinta for patients with acute ischemic stroke or transient ischemic attack, and the THEMIS study in patients with Type 2 diabetes and coronary atherosclerosis. These studies form part of PARTHENON, AstraZeneca's largest ever clinical trial programme, involving more than 80,000 patients worldwide. The programme also includes two trials that have recently completed recruitment; EUCLID for patients with Peripheral Artery Disease and PEGASUS, studying Brilinta for secondary prevention in patients with previous myocardial infarction. Headline results for PEGASUS are expected in the first quarter of 2015.

In 2011, the US Food and Drug Administration approved Brilinta for the treatment of patients with acute coronary syndrome (ACS). Brilinta has been approved by regulatory authorities in over 100 countries and is included in 11 major ACS treatment guidelines globally, including six established US treatment guidelines. The trial manuscript from the PLATO Executive Committee was first published in the New England Journal of Medicine. Following additional rigorous peer-review, over 30 PLATO sub-analyses articles have subsequently been published. The combination of these global reviews makes the PLATO data set one of the most widely analysed clinical trials.

About the civil investigative demand
On 21 October 2013, AstraZeneca received a civil investigative demand from the US Department of Justice seeking documents and information related to the PLATO trial. AstraZeneca has cooperated with the government enquiry, which focused on questions that have been raised previously in public about the trial. Similar questions have been responded to by the independent PLATO Executive Committee which led the clinical trial.

About the PLATO trial
PLATO was a large (18,624 patients in 43 countries), head-to-head patient outcomes study of BRILINTA vs. clopidogrel, both given in combination with aspirin and other standard therapy. The trial was designed to establish whether BRILINTA plus aspirin could achieve a clinically meaningful reduction in cardiovascular (CV) events in acute coronary syndrome (ACS) patients, above and beyond that afforded by clopidogrel plus aspirin. Patients were treated for at least 6 months and up to 12 months.

BRILINTA plus aspirin has been proven clinically superior to clopidogrel plus aspirin, in reducing thrombotic CV events, including CV death, at 12 months, based on data from the PLATO trial.

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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19 August 2014

-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 August 2014

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