GLAXOSMITHKLINE PLC
Form 6-K
November 12, 2013

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 period ending November 2013

GlaxoSmithKline plc
(Name of registrant)

980 Great West Road, Brentford, Middlesex, TW8 9GS
(Address of principal executive offices)

Indicate by check mark whether the registrant files or
will file annual reports under cover Form 20-F or Form 40-F

Form 20-F x Form 40-F

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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

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To be issued: 12 November 2013, London UK

GSK announces top-line results from pivotal Phase III study of darapladib in chronic coronary heart disease

GlaxoSmithKline (LSE:GSK) today announced top-line results from the Phase III STABILITY trial (STabilisation of Atherosclerotic plaque By Initiation of darapLadIb TherapY), evaluating the efficacy of its investigational Lp-PLA2 inhibitor darapladib in adults with chronic coronary heart disease (CHD). Darapladib is not approved for use anywhere in the world.

The study did not meet the primary endpoint measure, which was time to first occurrence of any major adverse cardiovascular event (MACE) from the composite of myocardial infarction (heart attack), stroke, and cardiovascular death (relative risk reduction of 6%; p=0.199). There were greater reductions (nominal p<=0.05) in some of the pre-defined secondary endpoints that require further analysis. Additional data will be forthcoming from the second Phase III study, SOLID-TIMI 52.

In STABILITY, the overall safety profile showed no major imbalance in serious adverse events between the active and placebo groups. Frequently reported adverse events included diarrhoea and odour which occurred at a similar frequency to that seen in Phase II. Further analysis of the data is ongoing.

Commenting on the results, Patrick Vallance, President of Pharmaceuticals R&D,said "Given the level of patient need in this area, we continue to investigate the role of Lp-PLA2 inhibition in coronary heart disease and other diseases. We will now work to better understand the data, including evaluation of the patient sub-groups, and await the outcome of a second Phase III study of darapladib in acute coronary syndrome, called SOLID-TIMI 52, to determine our next steps."

Full results of the STABILITY study will be submitted for presentation at a scientific meeting in 2014. The data from this study will contribute to any future regulatory submissions for darapladib.

S M Bicknell
Company Secretary

12 November 2013

About darapladib and atherosclerosis
Darapladib is a selective and orally active inhibitor of Lp-PLA2 (lipoprotein-associated phospholipase A2) currently being investigated as a potential agent for the reduction of cardiovascular events in patients with coronary heart disease. Lp-PLA2 is an enzyme that is found in blood and in atherosclerotic plaques. Atherosclerosis is characterized by the build-up of plaques of fat, cholesterol and other substances within the walls of arteries and is, in part, an inflammatory disease. When these plaques rupture they can block vital blood vessels, causing acute coronary syndromes (heart attacks) and strokes. Elevated Lp-PLA2 activity has been implicated in the development and progression of atherosclerosis.

About STABILITY trial design and the Phase III programme

STABILITY is the first of two Phase III studies. It was a randomised, placebo-controlled double-blind, parallel group multi-centre, event-driven study in adults with chronic coronary heart disease. Patients were randomised to receive either 160mg darapladib or placebo in addition to standard of care. Standard of care could include a statin, aspirin and blood pressure medications. The study enrolled more than 15,000 patients across 39 countries and continued until 1,500 major adverse cardiovascular events had occurred.

The primary endpoint was the composite of major adverse cardiovascular events (MACE): CV death, nonfatal myocardial infarction, and nonfatal stroke. The key secondary endpoints included major coronary events, total coronary events, individual components of MACE, and all-cause mortality.

The study design of STABILITY was published in the October 2010 edition of the American Heart Journal (H. White et al).

The second Phase III study, SOLID-TIMI 52, evaluating the efficacy of darapladib in patients with acute coronary syndrome, is ongoing and expected to complete in 2014. This trial has enrolled over 13,000 patients in 36 countries. The study design of SOLID-TIMI 52 was published in the October 2011 edition of the American Heart Journal (M.L. O'Donoghue et al).

GlaxoSmithKline- one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

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Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK' s operations are described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2012.

Registered in England & Wales:
No. 3888792

Registered Office:
980 Great West Road
Brentford, Middlesex
TW8 9GS

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 authorised.

GlaxoSmithKline plc
(Registrant)

Date: November 12 2013

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc