GLAXOSMITHKLINE PLC
Form 6-K
May 13, 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 period ending May 2014

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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Issued: Tuesday 13 May 2014, London UK - LSE announcement

GSK announces phase III study with darapladib did not meet primary endpoint in patients following an acute coronary syndrome

GlaxoSmithKline (LSE/NYSE: GSK) today announced headline results from its second phase III study with darapladib, SOLID-TIMI 52, evaluating the efficacy of its investigational Lp-PLA2 inhibitor in adults following an acute coronary syndrome.

In the study, darapladib did not achieve the primary endpoint of a reduction of major coronary events versus placebo when added to standard of care. The overall safety profile for darapladib showed no major safety concerns and was generally consistent with the safety data seen in the previously reported phase III study, STABILITY. Further analysis of the data is ongoing. Darapladib is not approved for use anywhere in the world.

Acute coronary syndrome is a term used to describe situations or events, including heart attack, where there is a sudden reduction of blood flow to the heart. Initial presentation by a patient with acute coronary syndrome results in a diagnosis of coronary heart disease.

Patrick Vallance, GSK's President of Pharmaceuticals R&D, commented:

"We are disappointed that the outcome of this second phase III study with darapladib does not support a regulatory submission in atherosclerosis. Our phase III programme for darapladib would not have been possible without the generous participation of more than 30,000 patients with coronary heart disease and their families, and we are most grateful for their participation. We will now work to further analyse the data and better understand the findings."

The primary endpoint measure in the SOLID-TIMI 52 study was time to first occurrence of any event from the composite of coronary heart disease death, myocardial infarction (heart attack) and urgent coronary revascularisation (medical procedures performed to restore normal blood flow in patients with atherosclerosis) for myocardial ischemia. Full results of the SOLID-TIMI 52 study will be presented at a scientific meeting.

About the SOLID-TIMI 52 trial and the phase III programme

SOLID-TIMI 52 (Stabilisation Of pLaques usIng Darapladib - Thrombolysis In Myocardial Infarction 52) is the second of two event-driven phase III studies with darapladib in coronary heart disease.

In November 2013, GSK announced results of the first study, STABILITY, which showed that darapladib did not achieve a statistically significant reduction in the primary endpoint of major adverse cardiovascular events (comprised of cardiovascular death, myocardial infarction and stroke) versus placebo in patients with chronic coronary heart disease.

In SOLID-TIMI 52, darapladib was tested as a long-term therapy in patients within 30 days of an acute coronary syndrome. The randomised, placebo-controlled, double-blind, parallel group multi-centre study enrolled more than 13,000 patients across 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).

The SOLID-TIMI 52 study was led by the TIMI Study Group, Brigham and Women's Hospital, Boston, Massachusetts.

About darapladib and atherosclerosis
Elevated Lp-PLA2 activity has been implicated in the development and progression of atherosclerosis. Darapladib is a selective and orally active inhibitor of Lp-PLA2 (lipoprotein-associated phospholipase A2). Lp-PLA2 is an enzyme that is found in blood and in atherosclerotic plaques. Atherosclerosis is an inflammatory condition characterised by the build-up of plaques of fat, cholesterol and other substances within the walls of arteries. When these plaques rupture they can block vital blood vessels, causing acute coronary syndromes (heart attacks) and strokes.

V A Whyte
Company Secretary
13 May 2014

GSK - 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. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2013.

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: May 13, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc