GLAXOSMITHKLINE PLC
Form 6-K
March 31, 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 March 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: 30 March 2014, London UK - LSE Announcement

GSK presents data from Phase III STABILITY study of darapladib in patients with chronic coronary heart disease

GlaxoSmithKline plc (LSE/NYSE: GSK) today presented datafrom the pivotal Phase III STABILITY study of darapladib at the American College of Cardiology 63rd Annual Scientific Session in Washington, DC. The data have also been published in the New England Journal of Medicine. Darapladib is not approved for use anywhere in the world.

This global, double-blind, event-driven trial randomized 15,828 patients with chronic coronary heart disease (CHD) to receive 160mg of darapladib or placebo once daily on a background of standard of care. The primary endpoint was time to first occurrence of any major adverse cardiovascular event (MACE) comprising cardiovascular death, myocardial infarction (MI) and stroke. Secondary endpoints included major coronary events (MCE) comprising CHD death, MI or urgent coronary revascularisation for myocardial ischemia; total coronary events comprising CHD death, MI, hospitalisation for unstable angina or any coronary revascularisation procedure; the individual components of MACE; and all-cause mortality.

No difference was seen in the treatment groups in the time to first occurrence of MACE. During 3.7 years median follow-up, the primary endpoint of MACE occurred in 9.7% of patients in the darapladib group and 10.4% of patients in the placebo group; hazard ratio (HR) 0.94, 95% confidence interval (0.85 - 1.03), p=0.199. HRs for individual components were cardiovascular death 0.96 (0.83 - 1.11), MI 0.89 (0.77 - 1.03) and stroke 1.01 (0.81 - 1.27).

Among the secondary endpoints, major coronary events occurred in 9.3% of patients taking darapladib versus 10.3% in the placebo group; HR 0.90 (0.82 - 1.00), p=0.045 (nominal significance). Similar effects were observed for the composite of total coronary events, which occurred in 14.9% of patients on darapladib versus 16.1% on placebo; HR 0.91 (0.84, 0.98), p=0.019 (nominal significance). There was no difference in all-cause mortality which occurred in 7.3% of patients in both groups.

The safety profile was well-characterised in this large outcome study. The frequency of serious adverse events was 43% in the darapladib group and 44% in the placebo group. Adverse events leading to study drug discontinuation occurred in 20% of patients on darapladib and 14% on placebo.

Dr Harvey White, MD, Director of Coronary Care Unit, Green Lane Cardiovascular Unit, Auckland City Hospital, Auckland, New Zealand, and the co-chair of the STABILTY study, commented:

"In the STABILITY study, the lack of effect on stroke was disappointing but not unexpected given the emerging epidemiology data. While the study didn't meet its primary endpoint, the effects of darapladib on the reduction of coronary events are of potential interest. These findings take us a step further towards defining which patients may benefit from treatment with darapladib."

Dr Murray Stewart, Senior Vice President, Metabolic Pathways Cardiovascular Therapy Area, added:

"STABILITY was a robust, large-scale cardiovascular outcomes study of a novel mechanism with the goal of providing incremental benefit above a high level of standard of care. Given the unmet medical need, the results of the

STABILITY study are important in understanding how this mechanism may impact the lives of patients with heart disease. We await the results of the second study, SOLID-TIMI 52, to better understand the findings."

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 characterised 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 (STtabilisation of Atherosclerotic plaque By Initiation of darapLadIb TherapY) is the first of two Phase III studies with darapladib. It was a randomised, placebo-controlled, double-blind 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 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 will evaluate the effects of darapladib in patients with acute coronary syndrome. The trial has enrolled over 13,000 patients across 36 countries. SOLID-TIMI 52 is ongoing and remains blinded. Results are expected in the second quarter of 2014. 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).

V A Whyte
Company Secretary
30 March 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.

Registered in England & Wales:
No. 3888792

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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: March 31, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc