GLAXOSMITHKLINE PLC
Form 6-K
November 25, 2016

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 24 November 2016

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

Issued: Thursday, 24 November 2016, London UK

GSK starts phase III programme with daprodustat for anaemia associated with chronic kidney disease

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced the start of a phase III development programme investigating daprodustat, an oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), as a treatment for anaemia associated with chronic kidney disease (CKD).

The phase III programme includes two studies evaluating the safety and efficacy of daprodustat compared to recombinant human erythropoietin:

ASCEND-D (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Dialysis) will enrol approximately 3,000 dialysis dependent subjects with anaemia associated with CKD switching from an erythropoietin-stimulating agent (ESA).

ASCEND-ND (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Non-Dialysis) will enrol approximately 4,500 non-dialysis dependent subjects with anaemia associated with CKD, and will include patients either switching from or naive to an ESA.

For both studies, the co-primary endpoints are time to first occurrence of major adverse cardiovascular events (MACE) and mean change in haemoglobin between the baseline and efficacy period (mean over Weeks 28-52). The studies will assess whether daprodustat is non-inferior to recombinant human erythropoietin on these endpoints as the primary analysis. If non-inferiority of the primary analysis is met, superiority will be assessed for the safety endpoint.

Julian Jenkins, Vice President and Medicine Development Leader responsible for the daprodustat programme, said: "For many patients with chronic kidney disease, treating their anaemia comes with risks associated with cardiovascular safety and injectable administration. The start of phase III studies of daprodustat is an important step in our work to explore whether daprodustat could address those risks and provide a potential alternative, oral treatment option."

The design of the phase III programme is based upon data from phase II clinical trials that were designed to characterise the dose-response relationship between daprodustat and haemoglobin at 4 weeks and assess the safety and tolerability of daprodustat following once-daily administration up to 24 weeks. Data from the 24-week phase II studies were presented at the American Society of Nephrology Kidney Week congress in Chicago, Illinois, earlier in November.

About anaemia

Anaemia is the term used to describe a decrease in normal levels of red blood cells. It is assessed by a patient's level of haemoglobin, the component of red blood cells that transports oxygen throughout the body. Anaemia commonly arises in patients with kidney dysfunction because the kidneys no longer produce sufficient amounts of erythropoietin, a hormone which stimulates red blood cell production. Patients with chronic kidney disease or kidney failure often experience varying degrees of anaemia as their disease progresses. This limits oxygen delivery to tissues, contributing to symptoms such as weakness and fatigue.

About daprodustat

Daprodustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor. Prolyl hydroxylase inhibition promotes the production of red blood cells that carry oxygen to where it is needed, similar to the effects that occur in the body at high altitude. Daprodustat is not approved as a treatment for anaemia or any other indication anywhere in the world.

About the phase III studies

The ASCEND-D study (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Dialysis) is a randomised, open-label (sponsor blind), active-controlled, parallel-group, multi-centre, event-driven study in dialysis subjects with anaemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin, following a switch from an erythropoietin-stimulating agent. The study aims to randomise approximately 3,000 subjects (1,500 per treatment arm). NCT02879305.

The ASCEND-ND study (Anaemia Studies in CKD: Erythropoiesis via a Novel PHI Daprodustat-Non-Dialysis) is a randomised, open-label (sponsor blind) active-controlled, parallel-group, multi-centre, event-driven study in non-dialysis subjects with anaemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin. The study aims to randomise approximately 4,500 subjects (2,250 subjects per treatment arm). NCT02876835.

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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GSK cautionary statement regarding forward-looking statementsGSK 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 2015.

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 24, 2016

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc