GLAXOSMITHKLINE PLC
Form 6-K
January 24, 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 January 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: Friday 24 January 2014, London UK - LSE Announcement

GSK receives positive opinion from the CHMP in Europe for once-weekly EperzanTM (albiglutide) for the treatment of type 2 diabetes

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending marketing authorisation for albiglutide, under the brand name EperzanTM. The CHMP opinion concerns albiglutide proposed as a once-weekly treatment to improve glycaemic control in adult patients with type 2 diabetes mellitus:

- As monotherapy, when diet and exercise alone do not provide adequate glycaemic control in patients for whom the use of metformin is considered inappropriate due to contraindications or intolerance
- As add-on combination therapy, in combination with other glucose-lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycaemic control.

Albiglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, is an investigational once-weekly type 2 diabetes treatment. GLP-1 is an important incretin hormone that helps normalise blood sugar levels.

"Today's positive opinion is a major milestone towards offering people with uncontrolled type 2 diabetes a new option to help manage their condition and we look forward to the final decision of the European Commission in the coming months", said Dr Carlo Russo, Senior Vice President, Research and Development at GSK. "Diabetes is a global health problem, affecting over 300 million people worldwide. Albiglutide has the potential to help many patients with type 2 diabetes who struggle to control their blood glucose levels."

A CHMP positive opinion is one of the last steps before marketing authorisation is granted by the European Commission. A final decision on marketing authorisation is anticipated during the first quarter of 2014.

Albiglutide is currently undergoing review by other authorities, including the US Food and Drug Administration (FDA) and the US Prescription Drug User Fee Act (PDUFA) target date is 15 April 2014. Albiglutide is not approved for use anywhere in the world.

The CHMP positive opinion is based on an evaluation of a comprehensive global programme of studies involving over 5,000 patients. The programme included eight Phase III trials evaluating albiglutide against commonly-used classes of type 2 diabetes treatment and involved patients at different stages of the disease, as well as those with renal impairment, for up to three years.

In clinical trials, acute pancreatitis has been reported in association with albiglutide and other GLP-1 receptor agonists. The most frequent adverse reactions during clinical trials, which occurred in ≥5% of patients receiving albiglutide, were diarrhoea, nausea, and injection site reactions. If approved, albiglutide will not be appropriate for use in patients with a history of serious hypersensitivity to albiglutide or any of its excipients.

B Kelly-Bisla
Corporate Secretariat
24 January 2014

About albiglutide
Albiglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, is an investigational biological product for the treatment of type 2 diabetes designed for once-weekly subcutaneous dosing. GLP-1 is a peptide that is normally secreted from the gastrointestinal tract during a meal which, in turn, helps release insulin to control blood sugar elevations after eating. In people with type 2 diabetes, GLP-1 secretion in response to a meal is reduced or absent.

Eperzan is a trademark of the GlaxoSmithKline group of companies.

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 http://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:
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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: January 24, 2014

By: SIMON BICKNELL

Simon Bicknell
Authorised Signatory for and on
behalf of GlaxoSmithKline plc