GLAXOSMITHKLINE PLC
Form 6-K
April 15, 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 April 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 15 April 2014, London UK - LSE Announcement

GSK receives US approval for once-weekly type 2 diabetes treatment, TanzeumTM (albiglutide)

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved TanzeumTM (albiglutide) for injection, for subcutaneous use, as a once-weekly treatment for type 2 diabetes. Tanzeum has been approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Albiglutide, a glucagon-like peptide-1 receptor agonist (GLP-1), is a biological product for the treatment of type 2 diabetes, administered once-weekly using an injector pen supplied with a 5mm 29-gauge thin-walled needle. Glucagon-like peptide-1 is an important incretin hormone that helps reduce blood glucose levels but, in people with type 2 diabetes, its production is often reduced or absent.

Vlad Hogenhuis, Senior Vice-President and Head, GSK Global Cardiovascular, Metabolic and Neurosciences Franchise, said: "Many type 2 diabetes patients struggle to keep their blood sugar within the recommended levels. We are pleased that the approval of Tanzeum provides an effective new weekly GLP-1 treatment option for appropriate patients in the US."

The FDA approval of albiglutide is based on the results of GSK's comprehensive Phase III Harmony programme, consisting of eight trials and involving over 5,000 patients, over 2,000 of whom were treated with Tanzeum. The Harmony studies evaluated albiglutide against commonly-used classes of type 2 diabetes treatment, including insulin, metformin, glimepiride and pioglitazone, in patients at different stages of the disease, as well as those with renal impairment.

Following this approval by the FDA, GSK anticipates the US launch of Tanzeum in the third quarter of 2014.

Albiglutide was licensed by the European Medicines Agency in March 2014, under the brand name Eperzan®, for use in adult patients with type 2 diabetes.

About diabetes
Diabetes is a global epidemic, affecting 382 million individuals globally, over 20 million of whom are in the US.1 Up to 95% of these patients have type 2 diabetes.1 Type 2 diabetes is a life-long, progressive and, in some cases, preventable condition characterized by high blood sugar levels, known as hyperglycemia. A lack of physical activity, obesity, increasing age, high blood pressure and genetics are known risk factors that can contribute to the development of type 2 diabetes.2,3 Treatment options include lifestyle changes such as increased physical activity and diet but, as the condition progresses, patients may require the addition of oral and injectable medications to control blood sugar levels and, ultimately, the use of insulin, either daily or with meals.

About TanzeumTM (albiglutide)
Tanzeum is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

LIMITATIONS OF USE
Tanzeum is notrecommended as first-line therapy for patients inadequately controlled on diet and exercise. Tanzeum has not been studied in patients with a history of pancreatitis. Tanzeum is not for treatment of type 1 diabetes mellitus

or diabetic ketoacidosis. Tanzeum has not been studied in patients with pre-existing severe gastrointestinal disease. Tanzeum has not been studied in combination with prandial insulin.

Full US Prescribing Information, including BOXED WARNING, Medication Guide and Instructions for Use will soon be available at us.gsk.com. Prior to the label being posted online, a copy of the label may be requested from the GSK Media or Investor Relations contacts listed in the "GlaxoSmithKline Inquiries" section at the end of this document.

Tanzeum has been approved with a Risk Evaluation and Mitigation Strategy (REMS), required by the FDA to ensure that the benefits of Tanzeum outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis. A non-promotional factsheet, reviewed by the FDA, with more detailed safety information is available at www.TANZEUMREMS.com.

Important Safety information for Tanzeum (albiglutide)
The following information is taken from the highlights section of the US Prescribing Information. Please see full Prescribing Information including boxed warning.

BOXED WARNING: RISK OF THYROID C-CELL TUMORS

Thyroid C-cell tumors have been observed in rodent studies with glucagon-like peptide-1 (GLP-1) receptor agonists at clinically relevant exposures. It is unknown whether Tanzeum causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. Tanzeum is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

CONTRAINDICATIONS
Do not use in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Do not use in patients with a prior serious hypersensitivity reaction to albiglutide or to any of the product components.

WARNINGS AND PRECAUTIONS
Pancreatitis: Discontinue promptly if suspected. Do not restart if confirmed. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Hypoglycemia: Can occur when used in combination with insulin secretagogues (e.g. sulfonylureas) or insulin. Consider lowering sulfonylurea or insulin dosage when starting Tanzeum.

Hypersensitivity Reactions: Discontinue Tanzeum if suspected. Monitor and treat promptly per standard of care until signs and symptoms resolve.

Renal Impairment: Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions.

Macrovascular Outcomes: There have been no clinical trials establishing conclusive evidence of macrovascular risk reduction with Tanzeum or any other antidiabetic drug.

ADVERSE REACTIONS
Adverse reactions, reported in ≥10% of patients treated with Tanzeum and more frequently than in patients on placebo, were upper respiratory tract infection, diarrhea, nausea, and injection site reaction.

TanzeumTM and Eperzan® are trademarks of the GlaxoSmithKline group of companies.

V A Whyte

Company Secretary

15 April 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.

References

1. IDF. Diabetes Atlas. Sixth Edition. 2013. Available at: http://www.idf.org/diabetesatlas/download-book. Last accessed April 2014
2. Elbein SC. Genetics Factors Contributing to Type 2 Diabetes across Ethnicities. Diabetes Sci Technol. 2009 July; 3(4): 685-689.
3. IDF. Types of diabetes. 2013. available at: http://www.idf.org/types-diabetes. Last accessed April 2014.

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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.

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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: April 15, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc