GLAXOSMITHKLINE PLC
Form 6-K
March 26, 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

--

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: 26 March 2014, London UK - LSE Announcement

GSK receives European authorisation for once-weekly type 2 diabetes treatment, Eperzan®(albiglutide)

GlaxoSmithKline plc (LSE/NYSE: GSK) today announced that the European Commission has granted marketing authorisation for its once-weekly diabetes treatment, Eperzan® (albiglutide). Eperzan is indicated for the treatment of type 2 diabetes mellitus in adults, to improve glucose control 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[1]
- 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.[1]

Vlad Hogenhuis, Senior Vice-President and Head, GSK Global Cardiovascular, Metabolic and Neurosciences (CVM&NS) Franchise, said, "Diabetes treatment can be challenging for healthcare professionals and patients, often involving complex daily regimens, with almost 50% of patients failing to meet their blood glucose targets.[2,3] The authorisation of albiglutide means that healthcare professionals and patients will have access to a new once-weekly treatment option that has shown effective blood glucose lowering with durable control and is generally well tolerated."[1,4]

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

The EMA authorisation of albiglutide is based on the results of the comprehensive Harmony programme, comprising eight Phase III studies. The Harmony programme involved over 5,000 patients and evaluated albiglutide against commonly-used classes of type 2 diabetes treatment, including insulin, in patients at different stages of the disease, as well as those with renal impairment. While many diabetes registration trials are just six months in duration, five of the Harmony trials included patient follow-up for up to three years.

GSK expects to launch albiglutide in several countries in Europe in Q3-4 2014 with additional launches to follow thereafter.

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.

Safety information concerning the use of albiglutide in Europe

Albiglutide is not appropriate for use in patients with a history of hypersensitivity to the active substance or any of its excipients.[1]

In clinical trials, the most serious adverse reaction observed with albiglutide was acute pancreatitis, which has also been reported with other GLP-1 receptor agonists. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, albiglutide should be discontinued; if pancreatitis is confirmed, albiglutide should not be restarted. Caution should be exercised in patients with a history of pancreatitis.[1]

The risk of hypoglycaemia is increased when albiglutide is used in combination with insulin secretagogues (such as sulphonylurea) or with insulin. Therefore, patients may require a lower dose of sulphonylurea or insulin to reduce the risk of hypoglycaemia.1

The use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. Albiglutide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and therefore it is not recommended in these patients. In Europe, due to very limited experience of albiglutide in patients with severe renal impairment (n=19) or on dialysis, its use in this population is not recommended.1

The most frequent adverse reactions during clinical trials, which occurred in ≥5% of patients receiving albiglutide, were diarrhoea, nausea, and injection site reactions, including rash, erythema or itching at the injection site.1

For the EU Summary of Product Characteristics for Eperzan, please visit http://ec.europa.eu/health/documents/community-register/index_en.htm. Prior to the label being posted online, a copy of the label may be requested from one of the GSK Media or Investor Relations contacts listed in the "GSK Enquiries" section at the end of this document.

Eperzan is a trademark of the GlaxoSmithKline group of companies.

V A Whyte
Company Secretary
26 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.

References

1. Eperzan EU Summary of Product Characteristics.
2. Ali MK, et al. Achievement of goals in US diabetes care. 1999-2010. N Engl J Med. 2013;368:1613-1624.
3. Fu AZ, Qiu Y, Radican L, Yin DD, Mavros P. Pre-existing cardiovascular diseases and glycemic control in patients with type 2 diabetes mellitus in Europe: a matched cohort study. Cardiovasc Diabetol. 2010 Apr 21; 9:15.
4. Eperzan European Public Assessment Report.

GSK enquiries:

UK Media enquiries:	David Mawdsley	+44 (0) 20 8047 5502	(London)
	Simon Steel	+44 (0) 20 8047 5502	(London)
	David Daley	+44 (0) 20 8047 5502	(London)
	Catherine Hartley	+44 (0) 20 8047 5502	(London)
	Sarah Spencer	+44 (0) 20 8047 5502	(London)
US Media enquiries:	Stephen Rea	+1 215 751 4394	(Philadelphia)
	Melinda Stubbee	+1 919 483 2510	

			(North Carolina)
	Mary Anne Rhyne	+1 919 483 0492	(North Carolina)
	Emily Beamer	+1 215 751 6622	(Philadelphia)
	Jennifer Armstrong	+1 215 751 5664	(Philadelphia)
Analyst/Investor enquiries:	Ziba Shamsi	+44 (0) 20 8047 3289	(London)
	Kirsty Collins (SRI & CG)	+44 (0) 20 8047 5534	(London)
	Tom Curry	+ 1 215 751 5419	(Philadelphia)
	Gary Davies	+44 (0) 20 8047 5503	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Lucy Singah	+44 (0) 20 8047 2248	(London)

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

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: March 26, 2014

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc