GLAXOSMITHKLINE PLC
Form 6-K
June 24, 2013

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 June 2013

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: Monday 24 June 2013, London UK

GSK announces data from five Phase III studies of albiglutide, an investigational once-weekly treatment for type 2 diabetes

Data from five long-term Phase III studies (Harmony 1 to 5) comparing albiglutide, an investigational glucagon-like peptide receptor agonist (GLP-1), to placebo and a range of active comparators were presented at the American Diabetes Association Meeting (ADA) in Chicago (21-25th June). The active comparators in the studies were insulin, a sulphonylurea (SU), a thiazolidinedione (TZD), and a dipeptidyl peptidase four inhibitor (DPP-4). Albiglutide is not approved for use anywhere in the world.

The primary efficacy endpoint for these studies was the change from baseline in HbA1c compared to placebo and/or active comparators assessed after one or two years of treatment. Secondary endpoints included fasting plasma glucose (FPG) and weight. These studies were specifically designed to assess durability of albiglutide effect on HbA1c and other continuous variables when used in various combination therapies, at different stages of the disease, and in various degrees of renal impairment. Albiglutide achieved the primary efficacy endpoint in these five studies, although a hierarchical analysis of noninferiority to pioglitazone was not met in one study, as noted below. The most commonly reported adverse reactions in these studies were gastrointestinal (GI) complaints, primarily nausea and diarrhoea, and injection site reactions.

In Harmony 1 (Abstract number: 2013-LB-5644), a 3-year, 52-week primary endpoint, randomised, double-blind, placebo-controlled study, patients inadequately controlled on a current regimen of pioglitazone with or without metformin were administered either 30mg albiglutide or placebo. At the 52 week primary endpoint, albiglutide combination therapy demonstrated a statistically significant reduction in HbA1c from baseline compared to placebo (treatment difference of -0.8% ($p<0.0001$)). Forty-four percent of the albiglutide patients achieved an HbA1c target of less than 7% compared to 15% of those on placebo. There was a non-significant difference in weight with albiglutide versus placebo (treatment difference: -0.2kg). Adverse events of nausea and vomiting were comparable between albiglutide and placebo, while diarrhoea (11.3% vs. 8.6%) and injection site reactions (11.3% vs. 7.9%) were higher for albiglutide vs placebo. The rate of severe hypoglycaemia in the albiglutide arm of the study was 1%.

Harmony 2 (Abstract number: 2013-LB-5749), a 3-year, 52-week primary endpoint randomised, double-blind, placebo-controlled study compared albiglutide 30mg or 50mg vs placebo in patients on diet and exercise in drug naïve patients. At 52 weeks, both albiglutide doses demonstrated statistically significant HbA1c reductions over placebo (-0.84% 30mg albi; -1.0% 50mg albi; $p<0.0001$). Weight (kg) decreased in all groups (-0.9/-0.4/-0.7kg placebo/30mg albi/50mg albi). GI adverse event rates for nausea (8%/10%/9%), diarrhoea (12%/10%/13%) and vomiting (1%/3%/3%) were similar across placebo/albi30mg/albi50mg, while injection site reactions (10%/18%/22%) were higher in the two albiglutide arms. There were no reports of severe hypoglycaemia in the albiglutide arm of the study.

Harmony 3 (Abstract number: 2013-LB-5750) was a 3-year, 104-week primary endpoint, randomised, double-blind, placebo- and active-controlled, parallel-group study comparing the efficacy and safety of albiglutide, sitagliptin, glimepiride, and placebo in subjects taking and inadequately controlled on metformin. At Week 104, the reduction in HbA1c was statistically significant in the albiglutide group compared to those treated with placebo(-0.9%; $p<0.0001$), sitagliptin (-0.4%; $p=0.0001$), orglimepiride (-0.3%; $p=0.003$). Weight loss in the albiglutide group was statistically significant compared to the glimepiride group (-2.4kg; $p<0.0001$) and similar to the sitagliptin (-0.4kg) and placebo (-0.2kg) groups. GI adverse events during 2 years of observation included nausea (11%/7%/6%/10%), vomiting (1%/4%/4%/6%) and diarrhoea (11%/9%/9%/13%) across the placebo/sitagliptin/glimepiride/albi arms; injection site

reactions were (5%/6%/8%/17%), respectively. There were no reports of severe hypoglycaemia in the albiglutide arm of the study.

In Harmony 4 (Abstract number: 2013-LB-5751), a 3-year, 52-week primary endpoint, randomised, open-label study, albiglutide was compared to insulin glargine, in subjects on metformin with or without an SU. Both groups achieved a similar reduction in HbA1c (-0.7% and -0.8% in the albiglutide and insulin glargine groups). Treatment difference 0.11% with 95% CI (0.04%, 0.27%) indicates non-inferiority of albiglutide versus insulin glargine. Patients on albiglutide lost weight (-1.1kg) while those on insulin glargine experienced weight gain (+1.6kg) with a treatment difference of 2.6kg ($p<0.001$). GI adverse events though week 52 for albiglutide/glargine arms included nausea (9.9%/3.7%), vomiting (3.8%/3.7%) and diarrhoea (7.5%/4.1%). Injection site reactions were higher for albiglutide vs. glargine (13.9% vs. 8.7%, respectively). The rate of severe hypoglycaemia in the albiglutide arm of the study was 0.4%.

The Harmony 5 study (Abstract: 2013-LB-5752) was a 3-year, 52-week primary endpoint, randomised, double-blind study to evaluate the efficacy and safety of albiglutide compared to placebo and pioglitazone (pio) in patients currently on a background therapy of metformin and glimerpiride. Stepwise statistical analysis was first versus placebo, followed by noninferiority (margin 0.30%) testing vs pio. At Week 52, the reduction in HbA1c in the albiglutide group was statistically significant versus the placebo group (-0.9%; $p<0.001$). Non-inferiority was not achieved versus the pio group (0.3%; $p=0.27$). GI adverse events at Week 52 for nausea (3.5%/4.3%/9.6%), diarrhoea (2.6%/5.4%/8.9%) and vomiting (0.9%/1.8%/2.6%) across the placebo/pio/albiglutide arms were higher for albiglutide, as were injection site reactions (3.5%/3.2%/12.9%). The rate of severe hypoglycaemia in the albiglutide arm of the study was 0.4%.

Data from one other Phase III study was also presented at the ADA meeting, Harmony 8 (68-OR), a 52-week controlled trial in which albiglutide was compared to a DPP-4 inhibitor, sitagliptin, in patients with renal impairment (results previously announced).

About the Harmony Phase III programme
The Phase III clinical development programme for albiglutide comprised eight individual studies (Harmony 1 to Harmony 8) involving over 5,000 patients. The programme investigated the efficacy, tolerability and safety, including cardiovascular safety, of albiglutide as mono- and add-on therapy, in patients with type 2 diabetes. All eight studies have completed.

About Albiglutide
Albiglutide, a 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. Albiglutide is currently undergoing regulatory review for the treatment of type two diabetes in the US and European Union.

V A Whyte
Company Secretary

24 June 2013

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 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:
No. 3888792

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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: June 24, 2013

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc