GLAXOSMITHKLINE PLC
Form 6-K
July 11, 2012

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 July 2012

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: Wednesday 11 July 2012, London UK - LSE announcement

GSK announces positive data from Harmony 8 and completion of clinical registration package for albiglutide in type 2 diabetes

GlaxoSmithKline (GSK) today announced that data have been received from the Phase III Harmony 8 study and from the event driven meta-analysis for assessment of cardiovascular safety conducted across the albiglutide clinical programme. These data are the final elements required to complete the clinical registration package. With these data now available and anticipating completion of the chemistry and manufacturing package in the next few months, GSK intends to commence global regulatory submissions for its investigational glucagon-like peptide-1 (GLP-1) receptor agonist albiglutide for the treatment of type 2 diabetes in early 2013. Albiglutide is not yet approved as a treatment for type 2 diabetes or any other indication anywhere in the world.

The Harmony 8 study is a 52-week randomised, double-blind, active-controlled, parallel-group, multicenter study, comparing albiglutide to a DPP-4 inhibitor, sitagliptin, in type 2 diabetes patients with renal impairment (n=507). It is the first completed study of a GLP-1 agonist to assess efficacy and safety across the spectrum of renal impairment from mild to severe, and the third of eight Harmony Phase III studies to complete. At the 26-week primary endpoint, albiglutide showed clinically and statistically significant reductions in HbA1c from baseline (8.08% for albiglutide and 8.22% for sitagliptin) and superiority versus sitagliptin (reduction of 0.83% vs 0.52%; $p<0.0001$ for non-inferiority and $p=0.0003$ for superiority). At the primary endpoint, weight loss was significantly greater in the albiglutide group than the sitagliptin group (-0.79kg vs -0.19kg; $p=0.0281$). During the full 52-week treatment period, albiglutide was generally well tolerated with diarrhoea being the most common adverse event for albiglutide (10%) vs sitagliptin (6.5%). Nausea and vomiting rates were relatively comparable across the albiglutide and sitagliptin treatment arms (4.8% vs. 3.3% for nausea; 1.6% vs. 1.2% for vomiting respectively).

A meta-analysis which demonstrates that a therapy will not result in an unacceptable increase in cardiovascular risk is required by the FDA for the registration and approval of any product for the treatment of type 2 diabetes in the US. The EMA has announced a similar safety assessment requirement for such treatments. For the albiglutide meta-analysis, an independent clinical endpoints committee adjudicated cardiovascular events across all eight Phase III Harmony studies involving approximately 5,000 patients and from one Phase II study. This analysis has now been completed and rules out excess cardiovascular risk according to a threshold pre-specified by the FDA. Analyses of the data support progression to submission and will be presented to health authorities in the coming months.

Detailed analysis of the full data set from Harmony 8 and the cardiovascular meta-analysis will be conducted in the coming months and the data will be submitted for presentation at scientific meetings in 2013 as appropriate.

In addition to data from Harmony 8 and the CV meta-analysis, the clinical registration package will also include data from two other completed Phase III studies Harmony 6 and 7 (presented at the American Diabetes Association meeting (ADA) in June 2012) and primary endpoint data from five remaining Phase III studies, Harmony 1 to 5. These data are currently in-house and support progression to registration; however as the five studies will not be completed until early 2013, the data have to remain confidential to protect the integrity of the ongoing blinded studies and in line with our agreement with regulatory authorities.

About the Harmony 8 study

The Harmony 8 study enrolled 507 patients with mild, moderate and severe renal impairment (glomerular filtration rate (GFR) of ≥ 15 and < 90 mL/min/1.73m2). Patients were randomised to receive albiglutide (30mg weekly with up-titration to 50mg weekly based on glycemic response) plus sitagliptin matching placebo, or sitagliptin (as per label: 25 to 100mg depending on degree of renal insufficiency) plus albiglutide matching placebo. Patients were treated for 52 weeks and the primary endpoint was a comparison between albiglutide and sitagliptin in the reduction of HbA1c from baseline at Week 26; secondary endpoints included other parameters of glucose control, weight, and safety and tolerability.

About the Harmony Phase III programme

The Phase III clinical development programme for albiglutide comprises eight individual studies, known as Harmony 1 to Harmony 8, and involvesapproximately 5,000 patients, The programme is investigating the efficacy, tolerability and safety, including cardiovascular safety, of albiglutide as mono- and add-on therapy, in patients with type 2 diabetes. A majority of the studies include active comparators, including a sulphonylurea, a thiazolidinedione (TZD), insulin and a dipeptidyl peptidase four inhibitor (DPP-4).

About albiglutide

Albiglutide is an investigational biological, injectable form of human GLP-1. GLP-1 is a peptide that acts throughout the body to help maintain normal blood-sugar levels and to control appetite. Normally, GLP-1 levels rise during a meal to help the body use and control the elevation in blood sugar levels. However, GLP-1 is rapidly degraded, resulting in its short duration of action. In people with type 2 diabetes, GLP-1 secretion in response to a meal is reduced. Albiglutide is an investigational medicine which fuses human GLP-1 to human albumin. It is designed to extend the action of GLP-1 and has potential to allow for weekly injections.

GSK is developing albiglutide as a once-weekly injection using a pen injector to allow reconstitution by the patient and a fine gauge needle for subcutaneous administration.

V A Whyte
Company Secretary
11 July 2012

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
Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, 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 'Risk factors' in the 'Financial review & risk' section in the company's Annual Report 2011 included as exhibit 15.2 to the company's Annual Report on Form 20-F for 2011.

Registered in England & Wales:
No. 3888792

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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: July 11, 2012

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc