GLAXOSMITHKLINE PLC
Form 6-K
April 03, 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 April 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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GSK receives further data from phase lll studies of albiglutide in type 2 diabetes

- Data from seven studies support progression towards regulatory filings

GlaxoSmithKline plc (GSK) today announced that topline results have been received from seven of the eight 'Harmony' Phase III studies investigating the use of albiglutide in type 2 diabetes. Albiglutide is an investigational once weekly glucagon-like peptide-1 (GLP-1) agonist.

In Harmony 6, the second of the phase III 'Harmony' studies to complete, albiglutide was compared to preprandial insulin, each administered on top of long-acting insulin glargine. In this study, the first of its kind for the class, albiglutide produced clinically significant reductions in HbA1c from baseline and non-inferiority versus preprandial lispro insulin after 26 weeks of treatment, achieving theprimary endpoint.

Results showed a reduction in HbA1c from baseline of 0.82% for patients receiving albiglutide compared to a reduction of 0.66% for preprandial lispro insulin ($p<0.0001$ for non-inferiority). Weight change from baseline was -0.73kg in the albiglutide arm and +0.81kg in the preprandial lispro insulin arm ($p<0.0001$ for treatment difference). The most common adverse events observed more frequently in the albiglutide arm than the comparator arm, in this 52 week study, were gastrointestinal in nature; nausea (13% for albiglutide versus 2.1% for preprandial lispro insulin) and vomiting (7% for albiglutide versus 1.4% for preprandial lispro insulin).

Initial data from the first study to complete, Harmony 7, a head-to-head study comparing albiglutide to once-a-day liraglutide, were announced in November 2011.

Today, GSK also announced that 2 year data read-outs from five ongoing phase III studies (Harmony 1 through Harmony 5) have been received. These read-outs present the final results for primary endpoint data up to two years. As the five ongoing studies have not completed, these data have to remain confidential to protect the integrity of the ongoing blinded studies and in line with our agreements with regulators. Nevertheless, the individual study data provide an early indication of the profile of the investigational product, broadly aligned with the results of the two completed studies. These two year data support progression and will be used for regulatory filings.

Harmony 8 will complete in mid 2012 and the five ongoing studies will complete in early 2013. The Harmony programme was designed to permit assessment of safety and durability of glycemic control after long-term use. The studies will provide data on the effect of albiglutide over three years, the first GLP-1 agonist to do so.

GSK has now reviewed primary endpoint data (6 months to 2 years) on the efficacy and safety of albiglutide, verses placebo and active controls, across seven Phase III studies. Based on these data, a better understanding of the profile of albiglutide in type 2 diabetes is emerging. The data reviewed to date support progression to regulatory submissions, as a possible once-weekly treatment for type 2 diabetes. As well as the full data set from Harmony 6, 7 and 8 and the 2 year data currently in-house from the five ongoing studies, a meta-analysis of cardiovascular safety data will be required to complete the registration package, consistent with FDA guidelines.

GSK anticipates data from both Harmony 6 and Harmony 7 will be presented at a scientific meeting in 2012. Results from the other six studies will be submitted for presentation and publication, once the studies complete.

V A Whyte

Company Secretary
3 April 2012

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.

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. The primary efficacy endpoint for all studies is the change from baseline in HbA1c compared to placebo and/or active comparators. A majority of the studies will include active comparators, including sulphonylurea, thiazolidinedione (TZD), insulin and a dipeptidyl peptidase four inhibitor (DPP IV).

The individual phase III studies are due to complete from late 2011 through early 2013. Harmony 6 and Harmony 7 have completed. One study (Harmony 8) will complete in 2012. The remaining five studies are expected to complete by early 2013; these ongoing studies have a primary efficacy endpoint set at between one and two years, and this timepoint has now been reached for each of these studies. As per the study protocols, these studies will remain blinded past the primary efficacy endpoint until completion, which for most studies is three years.

About albiglutide

Albiglutide is an investigational biological, injectable form of human GLP-1 and is not currently approved anywhere in the world. 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 utilise 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 have the potential to extended duration of action and allow for weekly or less-frequent injections.

GSK is developing albiglutide as a once-weekly subcutaneous injection. All of the medication is contained within a proprietary injector pen for simple reconstitution and subcutaneous administration using a fine gauge needle by the patient.

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

GlaxoSmithKline
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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 'Business Review' in 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
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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: 03 April 2012

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc