GLAXOSMITHKLINE PLC
Form 6-K
July 15, 2010

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 2010

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 July 14, 2010 Philadelphia U.S.

GlaxoSmithKline statement in response to FDA Advisory Committees' vote on safety of Avandia® (rosiglitazone)

GlaxoSmithKline [NYSE: GSK] confirmed today that a joint advisory committee to the U.S. Food and Drug Administration (FDA) voted to allow Avandia to remain on the market. Committee members voted for recommendations ranging from making no changes to the current label, to revising the label with additional warnings and restrictions (20) to withdrawal from the U.S. market (12).

"Following today's recommendations, w
e will, of course, continue to work with the FDA in the best interest of diabetes patients who face this chronic and serious disease,"
Dr. Ellen Strahlman, GSK's Chief Medical Officer, said.
"Patients taking Avandia should speak with their physician about their treatment and any questions they may have regarding the safety of the medicine."
The recommendation of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will now be considered by the FDA in making its final decision.
Pending the FDA's decision, Avandia remains available to physicians and appropriate patients as an option to help control blood sugar in patients with type 2 diabetes.
Strahlman continued: "GSK is dedicated to sharing data about its medicines transparently and in a timely manner.
We remain fully committed to maintaining best practice disclosure of clinical data to serve the interests of regulators, physicians and patients."
Avandia is one of the most extensively researched diabetes medicines and has been studied in more than 50,000 patients.
The company has consistently shared data with the FDA and worked with the agency to update the label for Avandia as new data became available.
GSK's view remains that controlled clinical trials are the most rigorous form of scientific evaluation that can be used to assess the benefits and risks of medicines.
Results from
six controlled clinical trials have been reported since the FDA last reviewed questions about the cardiovascular safety of Avandia in 2007. Together, these trials show that Avandia does not increase the overall risk of heart attack, stroke or death. As a result, we
believe that when used in the appropriate patient and in accordance with labeling, Avandia is a safe and effective treatment option for type 2 diabetes.
"We would like to acknowledge the efforts made by the FDA to apply scientific rigour to the debate and understanding of the
benefit-risk profile of Avandia
," Strahlman concluded.

About GlaxoSmithKline

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 more information please visit:
us.gsk.com
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Important safety information for
Avandia
® (rosiglitazone maleate)

AVANDIA can cause or worsen heart failure. If you have severe heart failure (very poor pumping ability of the heart) you cannot be started on AVANDIA. AVANDIA is also not recommended if you have heart failure with symptoms (such as shortness of breath or swelling) even if these symptoms are not severe.
AVANDIA may increase your risk of other heart problems that occur when there is reduced blood flow to the heart, such as chest pain (angina) or heart attack (myocardial infarction).
This risk appeared higher in patients taking medicines called nitrates or insulin.
If you have chest pain or a feeling of chest pressure, you should seek immediate medical attention, regardless of what diabetes medicines you are taking. If you take AVANDIA, tell your doctor right away if you: have swollen legs or ankles, a rapid increase in weight or difficulty breathing, or unusual tiredness; experience changes in vision; become pregnant.
Before taking AVANDIA
, review your medical history and tell your doctor if you:
.
Have heart failure or other heart problems, or are on any medicines for high blood pressure, high cholesterol or heart failure, or for prevention of heart disease or stroke.
.
Take insulin or nitrate medicines. Taking AVANDIA with insulin or nitrate is not recommended.
.
Have a type of diabetic eye disease called macular edema.
.
Have liver problems or had liver problems while taking REZULIN® (troglitazone).
.
Are pregnant or planning to become pregnant.
.
Are breastfeeding or planning to breastfeed.

Women taking AVANDIA should know that AVANDIA may increase the risk of pregnancy. More fractures have been observed in women taking AVANDIA. Other possible side effects of AVANDIA include anemia and hypoglycaemia. Your doctor should do blood tests to check your liver before you start AVANDIA and during treatment as needed.
Prescription AVANDIA, along with diet and exercise, helps improve blood sugar control in adults with type 2 diabetes.
For more information about AVANDIA, please see Medication Guide or full Prescribing Information at **www.AVANDIA.com**
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You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit
www.fda.gov/medwatch
, or call 1-800-FDA-1088.

S M Bicknell
Company Secretary

14 July 2010

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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 'Business Review' in the company' s Annual Report on Form 20-F for 2009.

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 14 2010

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc