GLAXOSMITHKLINE PLC
Form 6-K
April 27, 2009

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 2009

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 27 April 2009, London UK & Philadelphia, US - LSE Announcement

Large, long-term study shows dutasteride reduced prostate cancer risk in men at increased risk of the disease

- Primary endpoint achieved in REDUCE study as presented at American Urological Association

Headline data from the REduction by DUtasteride of prostate Cancer Events (REDUCE) trial was presented at the American Urological Association in Chicago, Illinois today. The study population was men between the ages of 50 and 75 who were at increased risk for prostate cancer with prostate specific antigen (PSA) levels between 2.5 and 10 ng/mL (men aged 50 to 60 years) and between 3.0 and 10.0 ng/mL (men aged greater than 60 years). REDUCE achieved its primary endpoint and demonstrated that dutasteride significantly reduced the risk of all biopsy-detectable prostate cancer by 23% ($p<0.0001$) over four years. A total of 1516 cancers were seen, with 659 in the dutasteride arm and 857 in the placebo arm.

A key secondary endpoint was Gleason score* at the time of diagnosis. The study endpoint showed no statistically significant difference in high grade tumours defined as Gleason scores 7-10 (233 out of 3406 patients or 6.8% for placebo, vs. 220 out of 3298 patients or 6.7% for dutasteride, $p= 0.81$) over the four year study period. In the Gleason scores 8-10, although a difference was seen over the four years, it was not statistically significant (19/3406 (0.6%) for placebo vs. 29/3298 (0.9%) for dutasteride, $p=0.15$).

The most common side effects reported, related to treatment, were erectile dysfunction (5.7% placebo vs. 9.0% dutasteride), decreased libido (1.6% placebo vs. 3.3% dutasteride), gynecomastia (1.0% placebo vs. 1.9% dutasteride). These adverse events are consistent with what has been previously reported in studies of dutasteride.

Further analysis will be included in the manuscript which will be prepared and submitted for publication in a peer review journal this year.

Dutasteride is not approved or licensed to treat or reduce the risk of prostate cancer.

About the REDUCE trial

The REDUCE (REduction by DUtasteride of prostate Cancer Events) trial is a international, randomised, double-blind, placebo-controlled, parallel group study of the efficacy and safety of dutasteride, 0.5 mg administered daily for four years to reduce the risk of biopsy-detectable prostate cancer.

The study included 8121 men between 50 and 75 years of age, 4072 and 4049 subjects in the placebo arm and dutasteride arms respectively in the efficacy population. Men less than 60 years old were required to have a PSA of 2.5 - 10 ng/mL, and men greater than or equal to 60 years were required to have a PSA of 3 - 10 ng/mL+.

In order to ensure that the patients included in the efficacy population of the study were at an increased risk for prostate cancer, all study subjects had to have had a single, negative biopsy within the 6 months prior to enrollment, and a prostate volume ≤ 80 cc. The single negative biopsy was to limit the likelihood of having existing prostate cancer but also to ensure sufficiently increased risk for prostate cancer at trial entry, which would have been reduced if the patient had experienced multiple negative biopsies.

About dutasteride

Dutasteride inhibits both type 1 and type 2 5-alpha reductase enzymes, which are responsible for converting testosterone to dihydrotestosterone (DHT), the most potent male hormone in the prostate.1 Basic science studies indicate that both types of the enzyme - type 1 and type 2 - are present in prostate tissue and that the type 1 form is increased in prostate cancer, including high grade cancer.

Dutasteride is indicated for the treatment of moderate-to-severe symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate. It has been shown to improve urinary symptoms, reduce the risk of acute urinary retention (AUR), and the risk of BPH-related surgery.2

Women and children should not take dutasteride. Women who are or could become pregnant should not handle dutasteride due to the potential risk of a specific birth defect. Possible side effects include sexual side effects and swelling or tenderness of the breast.

For more information see full prescribing information.

About prostate cancer

Prostate cancer is the second most commonly diagnosed cancer in men worldwide and it is responsible for over 221,000 deaths each year, equivalent to one every two minutes.3

Although many men will never experience complications or a reduced lifespan from prostate cancer, a diagnosis of prostate cancer can result in anxiety in some patients and caregivers.4

* The Gleason score describes how abnormal prostate cancer cells look under a microscope by assigning a score from 2 to 10, with 2 being the lowest and 10 being the highest.

+ PSA level is a risk factor for prostate cancer.

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

S M Bicknell

Company Secretary

27 April 2009

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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 2008.

References

1. Debruyne F, Barkin J, van Erps P, Reis M, Tammela TL, Roehrborn C. Efficacy and safety of long-term treatment with the dual 5 alpha-reductase inhibitor dutasteride in men with symptomatic benign prostatic hyperplasia. Eur Urol. 2004; 46:488-494; discussion 495

2. GSK. Avodart Summary of Product Characteristics. GSK UK, Uxbridge, Middlesex; 2008. http://emc.medicines.org.uk/medicine/11618

3. Parkin DM, et al. Global cancer statistics 2002. CA Cancer J Clin. 2005; 55: 74-108.

4. Mohile SG, Lachs M & Dale W. Sem Oncol 2008;35(6):597-617.

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: April 27 2009

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc