GLAXOSMITHKLINE PLC
Form 6-K
June 30, 2008

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 30, 2008

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 30 June 2008, London, UK & Philadelphia, US

Glaxo S mith K line Responds to FDA on CERVARIX®
and Plans to Submit Final Study Data for Approval

GlaxoSmithKline today provided the following update regarding its application to the U.S. Food and Drug Administration (FDA) for approval of CERVARIX®, its vaccine to prevent cervical cancer.

GSK has submitted its response to questions raised by the FDA in their Complete Response Letter, received in December, 2007. In addition, given that final data from GSK's Phase III pivotal efficacy study, HPV-008, are expected to be available later this year, GSK has decided to augment its application for approval with these data to ensure they are included in the U.S. label. GSK anticipates submitting these data in the first half of 2009. The timing depends on reaching a certain number of cases in order to conduct the final analysis. An FDA action on the application is expected to take up to six months following this submission. Interim data from this study were filed in the original application for the vaccine in March, 2007. The company does not expect that new clinical studies will be required for approval.

"Study 008 is a key study that will be completing later this year, and we expect the final results will strengthen the U.S. label for CERVARIX®," said Barbara Howe, M.D., Vice President and Director, North American Vaccine Development, GlaxoSmithKline. "We continue to have positive and productive discussions with the FDA and remain confident in the vaccine's safety and efficacy profile. We look forward to bringing this important new cervical cancer vaccine to girls and women in the U.S."

To date, GSK's cervical cancer vaccine has been approved in 67 countries around the world including the 27 member countries of the European Union, Mexico, Australia, Singapore and the Philippines. Licensing applications have been submitted in more than 35 additional countries including Japan. GSK also submitted the vaccine to the World Health Organization (WHO) for prequalification in September 2007.

Notes to Editors

Burden of Cervical Cancer

Worldwide, more than 500,000 women will be newly diagnosed with cervical cancer and over 280,000 women will die from it each year.[1] In the United States, after breast cancer, cervical cancer is the second leading cause of cancer death in women ages 20 to 39.[2]

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 company information, please visit www.gsk.com/media.

GlaxoSmithKline Biologicals (GSK Biologicals) is a leading global vaccine manufacturer committed to preventing disease in people of all ages with innovative vaccines and delivery systems. The division, headquartered in Belgium, is active in vaccine research, development and production with more than 30 vaccines currently available globally and 20 more in development. In 2007 GSK Biologicals distributed 1.1 billion doses of vaccines – an average of 3 million doses a day.

CERVARIX® is a registered trademark of the GlaxoSmithKline group of companies.

GSK cautionary statement regarding forward-looking statements

Under the safe harbour provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, 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 the Group's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2007.

References:

1. World Health Organization. Initiative for Vaccine Research. http://www.who.int/vaccine_research/diseases/hpv/en/ Accessed on May 2, 2007.

2. Jemal A, Murray T, Ward E, Sammuels A et al. Cancer Statistics, 2005. Cancer Journal for Clinicians 2005; 55; 10-30

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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 30, 2008

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc