GLAXOSMITHKLINE PLC
Form 6-K
March 30, 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 March 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,
30th
March 2009,
Philadelphia
US & London
UK

Cervarix
U.S.
regulatory update

GlaxoSmithKline submits final study data to FDA for cervical cancer vaccine

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 and cervical pre-cancer related to human papillomavirus types 16 and 18.

GSK has submitted final data from its Phase
III
pivotal efficacy study, HPV-008, to the FDA. The FDA has previously reviewed interim data from the same trial. FDA review of this type of Biologics License Application (BLA) submission is expected to take six months, according to agency regulations.

"We are pleased to have reached this significant milestone for CERVARIX®. The data submitted to the FDA reaffirm our confidence in the vaccine's safety and efficacy profile," said Barbara Howe, M.D., Vice President and Director, North American Vaccine Development, GlaxoSmithKline. "We will continue working closely with the FDA in order to make this vaccine available to help protect the cervical health of girls and women in the
U.S.
"

HPV-008 is a Phase
III
clinical study of more than 18,600 women between 15-25 years of age, from 14 countries across Europe
, Asia-Paci
fic and Latin and
North America
.
The primary objective was to assess vaccine efficacy in the prevention of high-grade pre-cancerous cervical lesions (
CIN
2+) caused by human papillomavirus types 16 or 18

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Secondary objectives included evaluation of vaccine efficacy in the prevention of pre-cancerous cervical lesions (
CIN
1+) and infections caused by virus types 16 or 18 or other cancer-causing virus types, as wel
l as immune response and safety.
GSK will submit the data to a peer-reviewed journal in the coming months.

The BLA for the vaccine includes safety, efficacy and immune response data from clinical trials in nearly 30,000 females and reflects an ethnically diverse population.

To date, GSK's vaccine has been approved in more than 90 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 20 additional countries including Japan. GSK also submitted the vaccine to the World Health Organization (WHO) for prequalification in September 2007.

S M Bicknell
Company Secretary
30 March 2009

Notes to Editors
Cervical Health Facts
- Worldwide, every two minutes a woman dies of cervical cancer; each year more than 500,000 women will be newly diagnosed and more than 280,000 women will die
.
In the
U.S.
, after breast cancer, cervical cancer is the leading cause of cancer-related death in women between the ages of 20 to 39 in the
United States
.
Also, in the
U.S.
each year there are an estimated 3.5 million abnormal Pap smears, and more than 1.5 million precancerous lesions are diagnosed
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GlaxoSmithKline Biologicals -
GSK's vaccines business is one of the world's leading vaccine companies and a leader in innovation. The company is active in the fields of vaccine research, development and production with over 30 vaccines approved for marketing and 20 more in development. Headquartered in
Belgium
, GSK Biologicals has 13 manufacturing sites strategically positioned around the globe. In 2008 GSK Biologicals distributed 1.1 billion doses of vaccines to 176 countries in both the developed and the developing world - an average of 3 million doses a day. Through its accomplished and dedicated workforce, GSK Biologicals applies its expertise to discover innovative vaccines that contribute to the health and well-being of people of all generations around the world.

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

CERVARIX® is a registered trademark of the GlaxoSmithKline group of companies
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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 Ann
ual Report on Form 20-F for 2008
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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: March 30, 2009

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc