GLAXOSMITHKLINE PLC
Form 6-K
October 16, 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 October 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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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.

Issued: October 16, 2009

FDA approves Cervarix, GlaxoSmithKline's cervical cancer vaccine

GlaxoSmithKline (NYSE: GSK) announced today that the U.S. Food and Drug Administration (FDA) has approved CERVARIX [Human papillomavirus bivalent (types 16 and 18) vaccine, recombinant] for the prevention of cervical pre-cancers and cervical cancer associated with oncogenic human papillomavirus (HPV) types 16 and 18 for use in girls and young women (aged 10-25).

"The approval of Cervarix will bring an important new cervical cancer vaccine to girls and young women," said Deirdre Connelly, President, North American Pharmaceuticals, GlaxoSmithKline. "Immunization with a vaccine such as CERVARIX - along with annual doctor visits and Pap tests - will help protect women from cervical cancer, the second leading cause of cancer death in women in their twenties and thirties."

CERVARIX was shown to be 93 percent efficacious in the prevention of cervical pre-cancers (cervical intraepithelial neoplasia 2+/ CIN 2+ or adenocarcinoma in situ) associated with HPV 16 or 18, in women without evidence of current infection with, or prior exposure to, the same HPV type at the time of vaccination. The majority (approximately 75 percent) of cervical cancers in North America are caused by HPV types 16 and 18.

The impact of CERVARIX against the overall burden of HPV-related cervical disease results from a combination of efficacy against, and disease contribution of, HPV-16, HPV-18, and oncogenic HPV types not included in the vaccine. In a subgroup of clinical trial participants without oncogenic HPV infection at the time of the first vaccination and without evidence of prior exposure to HPV 16 and 18, the vaccine showed an overall efficacy of 70 percent against pre-cancerous lesions, regardless of HPV type. In an additional analysis that assessed the impact of CERVARIX against specific HPV types not included in the vaccine, in women without oncogenic HPV infection with a specific type at the time of vaccination, approximately 89 percent efficacy was observed in the prevention of precancerous

lesions associated with HPV type 31, the third most common cancer-causing virus type in North America.

CERVARIX does not protect against disease caused by all HPV types. Approximately 100 types of HPV have been identified to date and, of these, approximately 15 virus types are known to cause cervical cancer.

"The FDA approval of a vaccine, such as CERVARIX, is an important development in the prevention of cervical cancer," said Levi Downs, M.D., M.S., F.A.C.O.G., assistant professor in the Department of Obstetrics, Gynecology and Women's Health, University of Minnesota, a clinical trial investigator and consultant for GSK. "The treatment of cervical pre-cancers and cancer can be devastating for women and their families. It's important for a vaccine to help reduce the need for the invasive procedures often used to treat cervical pre-cancers and cancers."

CERVARIX has a clinically acceptable safety profile. The most common local adverse reactions and general adverse events in ≥20% of clinical trial participants were pain, redness and swelling at the injection site, fatigue, headache, joint and muscle aching, and gastrointestinal symptoms.

The FDA's approval of CERVARIX was based on data from clinical trials in more than 30 countries involving a diverse population of nearly 30,000 girls and young women receiving CERVARIX.

CERVARIX is expected to be commercially available in the U.S. in late 2009.

SM Bicknell

Company Secretary

16th October 2009

About CERVARIX

CERVARIX is administered to young women between the ages of 10-25 in a three dose schedule that should be completed within six months of the initial dose. To date, CERVARIX has been approved in 100 countries around the world, including the 27 member states of the European Union (EU), Australia, Brazil, South Korea, Mexico and Taiwan. GSK also received World Health Organization (WHO) prequalification in July 2009.

CERVARIX (Human papillomavirus bivalent (types 16 and 18) vaccine, recombinant) is a registered trademark of the GlaxoSmithKline group of companies.

Important Safety Information

CERVARIX is contraindicated in patients with severe allergic reactions to any component of the vaccine.
CERVARIX is not recommended for use in pregnant women.
Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic
movements and other seizure-like activity, has been reported following vaccination with CERVARIX. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically
responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.
The most common local adverse reactions and general adverse events in ≥20% of subjects were pain, redness, and swelling at the injection site, fatigue, headache, myalgia, gastrointestinal symptoms, and
arthralgia.
Vaccination with CERVARIX may not result in protection in all vaccine recipients.

About Cervical Cancer

Women are at risk of HPV infection and cervical cancer throughout their lives. Approximately 100 types of HPV have been identified to date and, of these, approximately 15 virus types are known to cause cervical cancer. While the majority of cervical cancers in North America are caused by HPV types 16 and 18, approximately 25 percent of all cervical cancers are caused by other oncogenic HPV types. Infection with cancer-causing virus types can lead to abnormal Pap tests, cervical pre-cancers and cervical cancer.

Cervical cancer is the second leading cause of cancer death in women in their twenties and thirties. The American Cancer Society estimates that in 2009, in the U.S. approximately 11,000 women will be diagnosed with cervical cancer and 4,000 women will die from the disease, regardless of age. Worldwide, more than 500,000 women will be newly diagnosed with cervical cancer and 280,000 women will die from it each year.

GlaxoSmithKline Biologicals - GSK Biologicals, GlaxoSmithKline'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

Inquiries:

US Media inquiries:	Jeff McLaughlin	(919) 483 2839
	Sarah Alspach	(919) 483 2839
	Mary Anne Rhyne	(919) 483 2839
	Kevin Colgan	(919) 483 2839
US Analyst/ Investor inquiries:	Tom Curry	(215) 751 5419
	Jen Hill Baxter	(215) 751 7002
UK Media inquiries:	Philip Thomson	(020) 8047 5502
	Claire Brough	(020) 8047 5502
	Stephen Rea	(020) 8047 5502
	Alexandra Harrison	(020) 8047 5502
	Gwenan White	(020) 8047 5502
European Analyst/Investor inquiries:	David Mawdsley	(020) 8047 5564
	Sally Ferguson	(020) 8047 5543
	Gary Davies	(020) 8047 5503

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 20F for 2008.

GlaxoSmithKline plc
(Registrant)

Date: October 16, 2009

By: VICTORIA WHYTE

Victoria Whyte
Authorised Signatory for and on
behalf of GlaxoSmithKline plc