

GLAXOSMITHKLINE PLC  
Form 6-K  
May 15, 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 May 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:

Friday 15 May 2009

,  
London

UK

& Philadelphia

US

- LSE Announcement

**GlaxoSmithKline update:  
A (H1N1) influenza vaccine  
development**

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**GSK**

**has received**

**orders from**

**several**

**g**

**overnment**

**s aiming to**

**stockpile**

**a new**

**candidate A (H1N1) adjuvanted influenza vaccine as a precautionary measure**

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**Company**

**to manufacture the new vaccine, once virus seed is made available by the WHO**

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**Seasonal influenza vaccine production continues**

**GSK**

**is**

**committed to supporting governments and health authorities around the world to respond to the emergence of the new A (H1N1) influenza strain.**

Since the outbreak, the company has been in continuous discussions with governments and public health authorities, including the WHO, the US Centers for Disease Control and Prevention, the US Department of Health and Human Services and the European Centre for Disease Prevention and Control to help develop appropriate options to respond to the emergence of the new A (H1N1) influenza strain.

**A (H1N1) influenza candidate adjuvanted vaccine**

GSK expects to manufacture a candidate

A (H1N1)

adjuvanted

influenza vaccine once virus seed

is

made available by the

WHO. The first

doses of the vaccine are expected to be available four to six months later, subject to regulatory approval.

- The vaccine will comprise antigen of the recently isolated A (H1N1) influenza strain and also contain GSK's proprietary adjuvant system AS03. An adjuvant system can be added to the antigen at time of administration. In clinical studies using the H5N1 influenza strain, an adjuvanted formulation has been shown to stimulate a higher immune response while using a smaller amount of antigen as compared to a formulation without adjuvant. The adjuvant system therefore helps to increase the number of vaccine doses that can be produced.

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In addition, in clinical studies with the H5N1 influenza strain, the adjuvanted vaccine demonstrated the potential to provide protection even if the influenza strain drifts (changes slightly).

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- The new candidate vaccine will require regulatory approval. In 2008, GSK received a European licence for

a

pandemic vaccine based on a 'mock-up' dossier.

This approval, which was based on data involving the H5N1 influenza

strain, is expected to enable faster registration of this new A (H1N1) influenza vaccine and is currently being discussed with European regulatory authorities

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- To date, GSK has received interest from several governments aiming to stockpile the new candidate adjuvanted vaccine as a precautionary measure. These include:
  - Supplying the UK Government with 60 million doses of the candidate A (H1N1) adjuvanted influenza vaccine.
  - The French Government intend to purchase 50 million doses of the candidate A (H1N1) influenza vaccine.
  - The Government of Belgium intend to purchase 12.6 million doses of the candidate A (H1N1) influenza vaccine in order to stockpile and to protect, when needed, the total Belgian population.
  - An agreement with the Government of Finland to supply 5.3 million doses of H1N1 antigen, which is expected to be used in conjunction with the government's existing stockpile of GSK's adjuvant system.
- GSK has made substantial investments to expand capacity for its adjuvant system. As part of the company's commitment to maximising global manufacturing capacity of a pandemic vaccine, GSK is ready to engage in discussions with companies and governmental agencies that can combine the adjuvant system with alternatively sourced antigen.
- GSK is committed to addressing the needs of developing countries with use of this candidate adjuvanted

vaccine

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GSK  
will convert its  
intended donation  
to the WHO of 50 million doses of H5N1 pre-pandemic vaccine to the new candidate A (H1N1) adjuvanted influenza vaccine

once production begins

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- In the future, as capacity increases, GSK will supply the candidate A (H1N1) adjuvanted

influenza  
vaccine to developing countries under a tiered-pricing policy

based on World Bank classifications

and GAVI eligibility

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### **Seasonal influenza vaccine**

GSK will continue to produce its seasonal influenza vaccine for the 2009/2010 Northern Hemisphere influenza season as planned and expects to complete production of this vaccine by the end of July. The company also continues to supply seasonal vaccine for use in the Southern Hemisphere as it enters the winter season this year

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### **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](http://www.gsk.com)

**S M Bicknell**  
**Company Secretary**

15 May 2009

## Notes to Editors

- Adjuvants, from the Latin word *adjuvare* meaning 'to help', are compounds used to enhance a vaccine's ability to elicit a strong, durable, protective immune response making them more effective. Until recently, vaccine research and development focused nearly exclusively on the antigen, the target molecule that is selected to trigger a specific immune response in the body to protect against a particular disease. It is now widely accepted that adjuvants can also contribute substantially to the immune response induced by a vaccine.

- GSK is continuing discussions with other governments and public health authorities to increase production and supply of its anti-viral medication, *Relenza*.

*Relenza*

can both treat influenza (flu, infection caused by influenza virus) and reduce the chance of getting flu in the community and household settings. The flu is a highly contagious and potentially fatal disease caused by influenza types A and B. While some antiviral medications only protect against influenza A,

*Relenza*

is effective against both influenza A and B.

*Relenza*

is approved for the prophylaxis and treatment of influenza in children and adults.

- *Relenza* is an inhaled medicine delivered as a dry powder through a device called a *Diskhaler* to the surface of the upper respiratory tract, and may shorten the amount of time a person is sick if used within two days of onset of illness. *Relenza* belongs to a group of medicines called neuraminidase inhibitors. These medications attack the influenza virus itself - not just the symptoms - and prevent it from spreading inside your body.

## 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

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**References**

1. Leroux-Roels et al. Antigen sparing and cross-reactive immunity with an adjuvanted rH5N1 prototype pandemic influenza vaccine: a randomised controlled trial. *Lancet* 2007; 370 (9587): 580-89.
2. Leroux-Roels I et al, Broad Clade 2 Cross-Reactive Immunity Induced by an Adjuvant systemed Clade 1 rH5N1 Pandemic Influenza Vaccine PLoS ONE 3(2): e 1665. doi:10.1371/journal.pone.0001665

3.

Baras et al. Cross-protection against lethal H5N1 challenge in ferrets with an adjuvanted pandemic influenza vaccine. PLoS ONE 2008; 3 (1): e1401.

*Relenza*  
and  
*Diskhaler*  
are trademarks of GlaxoSmithKline

**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: May 15, 2009

By: VICTORIA WHYTE



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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc