

GLAXOSMITHKLINE PLC  
Form 6-K  
November 02, 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 November 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

Yes No x

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November

2009, London UK

& Philadelphia US - LSE Announcement

### **GlaxoSmithKline and Human Genome Sciences announce**

**positive results in second of two phase 3 trials of**

**BENLYST**

**A in systemic lupus erythematosus**

*- BENLYSTA (belimumab) 10 mg/kg plus standard of care met its primary efficacy endpoint by achieving a statistically significant improvement in patient response rate versus placebo plus standard of care at Week 52 in BLISS-76*

*- Primary efficacy endpoint met in two pivotal Phase 3 trials, as specified by Special Protocol Assessment agreement with FDA*

GlaxoSmithKline

PLC

(GSK) and Human Genome Sciences, Inc. (Nasdaq:

HGSI

) today announced that BENLYSTA™ (belimumab) met the primary endpoint in BLISS-76, the second of two pivotal Phase 3 trials in seropositive patients with systemic lupus erythematosus (

SLE

). BLISS-76 study results through 52 weeks showed that belimumab 10 mg/kg plus standard of care achieved a statistically significant improvement in patient response rate as measured by the

SLE

Responder Index at Week 52, compared with placebo plus standard of care. Study results also showed that belimumab was generally well tolerated, as demonstrated by a similar rate of discontinuations due to adverse events across treatment groups, with overall adverse event rates comparable between belimumab and placebo treatment groups.

"The BLISS-76 results confirm our view that BENLYSTA has the potential to become the first new approved drug in decades for people living with systemic lupus," said H. Thomas Watkins, President and Chief Executive Officer, HGS. "We take great pride in the innovation and scientific rigou

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r that has made it possible to bring BENLYSTA to this point. We plan to submit marketing applications in the first half of 2010, following discussions with regulatory authorities in the United States

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Europe

and other regions. We will continue to work with GSK to advance this drug to the market where it may benefit patients with significant need."

Carlo Russo, M.D., Senior Vice President, Biopharm Development, GSK, said, "The results from this second pivotal Phase 3 trial reinforce our belief that belimumab could deliver a significant therapeutic option for patients with lupus who have had no new treatment in 50

years. We look forward to continuing our collaboration with HGS in order to bring this important medicine to patients."

The data from the BLISS-76 study were analysed after 52 weeks, in accordance

with the study protocol, in support of a potential Biologics License Application in the United States and Marketing Authorisation Applications in Europe

and other regions. However, the BLISS-76 study is ongoing and will continue for 24 more weeks. Additional data will be available following completion of the full

76-week study period. Belimumab is an investigational drug and the first in a new class of drugs called BLyS-specific inhibitors. Belimumab is being developed by HGS and GSK under a co-development and commercialisation agreement entered into in August 2006.

### **Key Findings from BLISS-76**

"We are delighted that the efficacy of treatment with belimumab plus standard of care was superior to placebo plus standard of care in both BLISS-52 and BLISS-76, with overall adverse event rates comparable to placebo plus standard of care," said David C. Stump, M.D., Executive Vice President, Research and Development, HGS. "Belimumab met the primary endpoint in both pivotal Phase 3 trials, as specified by the Special Protocol Assessment Agreement with the FDA. We look forward to the full presentation of the BLISS-76 52-week results at an appropriate scientific meeting, hopefully in the first half of 2010."

### **Topline BLISS-76 results include:**

- Based on an intention-to-treat (ITT) analysis, belimumab 10 mg/kg met its primary efficacy endpoint of superiority versus placebo at Week 52. A statistically significant improvement was shown in patient response rate for belimumab

10 mg/kg plus standard of care, vs. placebo plus standard of care, as measured by the SLE

Responder Index at Week 52: 43.2% for 10 mg/kg belimumab, 40.6% for 1 mg/kg belimumab, and 33.8% for placebo ( $p=0.021$  and  $p=0.10$  for 10 mg/kg and 1 mg/kg belimumab, respectively vs. placebo). The 1 mg/kg dose plus standard of care did not achieve

a

statistically significant improvement in the current study. The

SLE

Responder Index defines patient response as an improvement in SELENA SLEDAI score of 4 points or greater, with no clinically significant BILAG worsening and no clinically significant worsening in Physician's Global Assessment.

- Results for pre

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specified major secondary efficacy endpoints were:

- The proportion of patients with a reduction in SELENA SLEDAI score of at least 4 points by Week 52, was 46.9% for belimumab 10 mg/kg, 42.8% for belimumab 1 mg/kg, and 35.6% for placebo ( $p=0.0062$  and  $p=0.087$  for belimumab 10 mg/kg and 1 mg/kg, respectively vs. placebo).

- Improvement from baseline in Physician's Global Assessment (

PGA

) at Week 24 was not statistically different between the belimumab and placebo treatment groups.

Mean improvement in

PGA

at Week 52, a pre

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specified although not a major secondary endpoint, was 0.49 for belimumab 10 mg/kg, 0.5

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for belimumab 1 mg/kg, and 0.4

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for placebo ( $p=0.12$  for belimumab 10 mg/kg and  $p=0.022$  for 1 mg/kg, respectively vs. placebo).

- At entry into the BLISS-76 study, approximately 46% of patients were receiving steroids at a prednisone-equivalent dose of at least 7.5 mg per day. Among these patients, the percentage of patients who had their average steroid dose reduced by at least 25% from baseline to 7.5 mg per day or less during the last 12 weeks of study was 16.7% for belimumab 10 mg/kg, 19.2% for belimumab 1 mg/kg, and 12.7% for placebo (not statistically significant vs. placebo).

- Improvement in health-related quality of life at Week 24 as measured by the SF-36 Physical

Component Summary (

PCS

) score was not significantly different among treatment groups. Mean improvement in the SF-36

PCS

score at Week 52, a pre

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specified

although not

major secondary endpoint, was 3.41 for belimumab 10 mg/kg, 4.37 for belimumab 1 mg/kg, and

2.85 for placebo ( $p=0.51$  for belimumab 10 mg/kg and  $p=0.012$  for 1 mg/kg, respectively vs.

placebo).

- In BLISS-76, belimumab was generally well tolerated, with rates of overall adverse events, serious and/or severe adverse events, all infections, serious and/or severe infections, and discontinuations due to adverse events comparable between treatment groups receiving belimumab plus standard of care and the treatment group receiving placebo plus standard of care. Serious and/or severe adverse events were reported in 26.8% of patients on belimumab and 24.0% of patients on placebo. Infections were reported in 72.1% of patients on belimumab and 67.3% of patients on placebo. Serious and/or severe infections were reported in 7.2% of patients on belimumab and 8.0% of patients on placebo. Serious and/or severe infusion reactions were reported in 1.1% of patients on belimumab and 0.

7

% of patients on placebo. Discontinuations due to adverse events were 7.

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% in the belimumab treatment groups and 7.6% in the placebo treatment group. Malignancies were reported by 2, 3, and 1 subjects in the belimumab 10 mg/kg, belimumab 1 mg/kg and placebo groups, respectively. There were three deaths in the study, with 1, 2, and 0 reported in the belimumab 10 mg/kg, belimumab 1 mg/kg and placebo groups, respectively.

"The lupus community has waited for decades for one positive Phase 3 trial of an investigative drug developed for lupus. Now we have two. Based on the data we now have in hand, we have cause for hope that belimumab may emerge as a significant new treatment for lupus," said Joan T. Merrill, M.D., a study investigator, Program

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Chair, Clinical Pharmacology Research Program

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, Oklahoma Medical Research Foundation, Oklahoma City, and Professor, Department of Medicine, University of Oklahoma Health Sciences Centre.

### ***About the BENLYSTA (belimumab) Phase 3 Development Programme***

The Phase 3 development program

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for belimumab includes two double-blind, placebo-controlled, multi-centre

Phase 3 superiority trials - BLISS-52 and BLISS-76 - to evaluate the efficacy and safety of belimumab plus standard of care, versus placebo plus standard of care, in seropositive (HEp-2

ANA

≥

1:80 and/or anti-dsDNA

≥

30 IU/mL) patients with

SLE

. This is the largest clinical trial program

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ever conducted in lupus patients.

BLISS-52 randomis

ed and treated 865 patients at 90 clinical sites in 13 countries, primarily in

Asia

,

South America  
and

Eastern Europe

. BLISS-76 randomis

ed and treated 819 patients at 136 clinical sites in 19 countries, primarily in

North America

and

Europe

. The design of the two trials is similar, but the duration of therapy in the two studies is different - 52 weeks for BLISS-52 and 76 weeks for BLISS-76. Data from BLISS-76 were

analys

ed after 52 weeks in support of a potential Biologics License Application in the

United States

and Marketing Authoris

ation Applications in

Europe

and other regions. HGS designed the Phase 3 program for belimumab in collaboration with GSK and leading international

SLE

experts, and the program is being conducted under a Special Protocol Assessment agreement with FDA.

The primary efficacy endpoint of BLISS-52 and BLISS-76 is the patient response rate at Week 52 as measured by the

SLE

Responder Index, which is defined by: (1) a reduction from baseline of at least 4 points on the SELENA SLEDAI disease activity scale (which indicates a clinically important reduction in

SLE

disease activity); (2) no worsening of disease as measured by the Physician's Global Assessment (worsening defined as an increase of 0.30 points or more from baseline); (3) no new BILAG A organ domain score (which indicates a severe flare of lupus disease activity) and no more than one new BILAG B organ domain score (which indicates a moderate flare of disease activity). Analysis for the primary endpoint is based on intention-to-treat and adjusted for baseline stratification factors, including SELENA SLEDAI score, proteinuria and race.

In each of the two Phase 3 trials, patients were

randomis

ed to one of three treatment groups: 10 mg/kg belimumab (BLISS-52, n=290; BLISS-76, n=273), 1 mg/kg belimumab (BLISS-52, n=288; BLISS-76, n=271), or placebo (BLISS-52, n=287; BLISS-76, n=275).

Patients are dosed intravenously on Days 0, 14 and 28, then every 28 days thereafter for the duration of the study. All patients receive standard of care therapy in addition to the study medication. Safety is reviewed by an independent Data Monitoring Committee throughout both studies.

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Company Secretary

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November 2009

**About BENLYSTA (belimumab)**

Belimumab is an investigational human monoclonal antibody drug that specifically recognizes and inhibits the biological activity of B-lymphocyte stimulator, or BLYS®. BLYS is a naturally occurring protein discovered by HGS that is required for the development of B-lymphocyte cells into mature plasma B cells. Plasma B cells produce antibodies, the body's first line of defence against infection. In lupus and certain other autoimmune diseases, elevated levels of BLYS are believed to contribute to the production of autoantibodies - antibodies that attack and destroy the body's own healthy tissues. The presence of autoantibodies appears to correlate with disease severity. Preclinical and clinical studies suggest that belimumab can reduce autoantibody levels in

SLE

. The results of two pivotal Phase 3 trials, BLISS-52 and BLISS-76, suggest that belimumab can reduce

SLE

disease activity.

### **About the Collaboration with GSK**

In August 2006, HGS and GSK entered into a definitive co-development and co-commerciali

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ation agreement under which HGS has responsibility for conducting the belimumab Phase 3 trials, with assistance from GSK. The companies will share equally in Phase 3/4 development costs, sales and marketing expenses, and profits of any product commercialized under the current agreement.

### **About Systemic Lupus Erythematosus**

Systemic lupus erythematosus (

SLE

) is a chronic, life-threatening autoimmune disease. Approximately five million people worldwide, including approximately 1.5 million in the

United States

, suffer from various forms of lupus, including

SLE

. Lupus can occur at any age, but appears mostly in young people ages 15 to 45. About 90 percent of those diagnosed with lupus are women. African-American women are about three times more likely to develop lupus, and it is also more common in Hispanic, Asian and American Indian women. Symptoms may include extreme fatigue, painful and swollen joints, unexplained fever, skin rash and kidney problems. Lupus can lead to arthritis, kidney failure, heart and lung inflammation, central nervous system abnormalities, inflammation of the blood vessels and blood disorders. For more information on lupus, visit the Lupus

Foundation of America at

[www.lupus.org](http://www.lupus.org)

, the Lupus Research Institute at

[www.lupusresearchinstitute.org](http://www.lupusresearchinstitute.org)

,

the National Institute of Arthritis and Musculoskeletal and Skin Diseases at

[www.niams.nih.gov](http://www.niams.nih.gov)

, or Lupus Europe at

[www.elef.rheumanet.org](http://www.elef.rheumanet.org)

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### **Conference Call**

HGS management will hold a conference call to discuss this announcement today at 8:15 AM

Eastern. Investors may listen to the call by dialling 800-753-9057 or 913-312-0718, passcode 9331404, five to 10 minutes before the start of the call. A replay of the conference call will be available within a few hours after the call ends. Investors may listen to the replay by dialling 888-203-1112 or 719-457-0820, confirmation code 9331404. Today's conference call also will be webcast and can be accessed at [www.hgsi.com](http://www.hgsi.com)

. Investors interested in listening to the live webcast should log on before the conference call begins to download any software required. Both the audio replay and the archive of the conference call webcast will remain available for several days.

### **About GlaxoSmithKline**

GSK Biopharm R&D is employing novel approaches to harness the therapeutic potential of biopharmaceuticals for the benefit of patients with serious autoimmune disease. This innovative research is one way GSK - one of the world's leading research-based pharmaceutical and healthcare companies - can deliver on its commitment to improving the quality of human life by enabling people to do more, feel better and live longer. For more information, visit GlaxoSmithKline on the World Wide Web at [www.gsk.com](http://www.gsk.com).

### **About Human Genome Sciences**

The mission of HGS is to apply great science and great medicine to bring innovative drugs to patients with unmet medical needs. The HGS clinical development pipeline includes novel drugs to treat lupus, hepatitis C, inhalation anthrax and cancer.

The Company's primary focus is rapid progress toward the commerciali  
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ation of its two lead drugs, BENLYSTA™ (belimumab) for lupus  
and ZALBIN™ (albinterferon alfa-2b  
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for hepatitis C. BENLYSTA has successfully met its primary endpoint in two pivotal Phase 3 trials in systemic lupus erythematosus, and the submission of marketing applications in the U.S.

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Europe

and other regions is planned in the first half of 2010.

ZALBIN has completed Phase 3 development, and the submission of global marketing applications is planned in fourth quarter 2009.

In May 2009, HGS submitted a Biologics License Application to the FDA for raxibacumab for the treatment of inhalation anthrax. In addition, HGS has substantial financial rights to certain products in the GSK clinical pipeline including darapladib, currently in Phase 3 development in patients with coronary heart disease, and Syncria® (albiglutide), currently in Phase 3 development in patients with type 2 diabetes.

For more information about HGS, please visit the Company's web site at

[www.hgsi.com](http://www.hgsi.com)

. Health professionals and patients interested in clinical trials of HGS products may inquire via e-mail to [medinfo@hgsi.com](mailto:medinfo@hgsi.com)

or by calling HGS at (877) 822-8472.



**GSK Contacts:**

UK Media enquiries:	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

		(
		919
US Media enquiries:	Nancy Pekarek	)
		483

		2839
	Mary Anne Rhyne	(919) 483 2839
	Kevin Colgan	(919) 483 2839
	Holly Russell	(919) 483 2839

European Analyst/Investor enquiries:	David Mawdsley	(020) 8047 5564
	Sally Ferguson	(020) 8047 5543
	Gary Davies	(020) 8047 5503

US Analyst/ Investor enquiries:	Tom Curry	(215) 751 5419
	Jen Hill Baxter	(215) 751 7002

**HGS Contacts**

:		
Media	Jerry Parrott	301-315-2777
	Vice President, Corporate Communications	
Investors	Peter Vozzo	301-251-6003
	Senior Director, Investor Relations	

**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.

**HGS**

**Safe Harbor Statement**

This announcement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The forward-looking statements are based on Human Genome Sciences' current intent, belief and expectations. These statements are not guarantees of future performance and are subject to certain risks

and uncertainties that are difficult to predict. Actual results may differ materially from these forward-looking statements because of Human Genome Sciences' unproven business model, its dependence on new technologies, the uncertainty and timing of clinical trials, Human Genome Sciences' ability to develop and commercialize products, its dependence on collaborators for services and revenue, its substantial indebtedness and lease obligations, its changing requirements and costs associated with facilities, intense competition, the uncertainty of patent and intellectual property protection, Human Genome Sciences' dependence on key management and key suppliers, the uncertainty of regulation of products, the impact of future alliances or transactions and other risks described in the Company's filings with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today's date. Human Genome Sciences undertakes no obligation to update or revise the information contained in this announcement whether as a result of new information, future events or circumstances or otherwise

### 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: November 02, 2009

By: VICTORIA WHYTE

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Victoria Whyte  
Authorised Signatory for and on  
behalf of GlaxoSmithKline plc