



## HUMAN GENOME SCIENCES AND GLAXOSMITHKLINE ANNOUNCE POSITIVE PHASE 3 STUDY RESULTS FOR BENLYSTA™

*- BENLYSTA (belimumab) met its primary efficacy endpoint by achieving a statistically significant improvement in patient response rate versus placebo in BLISS-52 -*

*- First drug for lupus to reach this advanced stage of clinical development and achieve positive results, in the largest randomized placebo-controlled clinical trial ever completed in SLE patients -*

**ROCKVILLE, Maryland, and LONDON, UK – July 20, 2009** – Human Genome Sciences, Inc. (Nasdaq: HGSI) and GlaxoSmithKline PLC (GSK) today announced that BENLYSTA™ (belimumab, formerly LymphoStat-B®) met the primary endpoint in BLISS-52, the first of two pivotal Phase 3 trials in patients with serologically active systemic lupus erythematosus (SLE). In the placebo-controlled BLISS-52 study, the results showed that belimumab plus standard of care achieved a clinically and statistically significant improvement in patient response rate at Week 52, compared with standard of care alone. Study results also showed that belimumab was generally well tolerated, with adverse event rates comparable between belimumab and placebo treatment groups.

“The BLISS-52 results demonstrated 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. “Given the limited treatment options currently available, patients would benefit greatly from potential new treatments. BENLYSTA is an outstanding example of the type of treatment HGS is working to develop and bring to patients. Assuming positive results in November from our second Phase 3 trial of BENLYSTA, we and GSK plan to submit marketing applications in the United States, Europe and other regions in the first half of 2010.”

Belimumab is an investigational drug and the first in a new class of drugs called BLYS-specific inhibitors. No new drug for lupus has been approved by regulatory authorities in more than 50 years. Belimumab is being developed by HGS and GSK under a co-development and commercialization agreement entered into in August 2006.

“Lupus is a chronic, often debilitating, and sometimes fatal illness that affects an estimated five million people worldwide and can have a devastating effect on both patients living with the disease and their families,” said Carlo Russo, M.D., Senior Vice President, Biopharm Development, GSK. “BENLYSTA is the first medicine being developed specifically for lupus that has reached this late stage of clinical development with positive results. We look forward to completing the pivotal studies, with the hope of bringing this potentially important therapeutic advance to patients suffering from SLE.”

### Key Findings from BLISS-52

“The BLISS-52 results support and extend the findings that emerged in the serologically active subgroup of SLE patients at Week 52 in our Phase 2 trial,” said David C. Stump, M.D., Executive Vice President, Research and Development, HGS. “We are delighted to report that the efficacy of treatment with BENLYSTA plus standard of care was superior in this study to that of placebo plus standard of care, while the safety profile was comparable overall to placebo. BENLYSTA met the primary endpoint in this Phase 3 study at a robust level of statistical significance. BENLYSTA also significantly reduced SLE disease activity versus placebo based on a number of other measures, including SELENA SLEDAI and Physician’s Global Assessment. Of note, a greater percentage of patients receiving BENLYSTA achieved a clinically meaningful reduction in steroid dose. We hope to have a full presentation of BLISS-52 results at an appropriate scientific meeting later in 2009.”

Topline BLISS-52 results include:

- Based on an intention-to-treat (ITT) analysis, belimumab met its primary efficacy endpoint of superiority versus placebo at Week 52. A clinically and statistically significant improvement was shown in patient response rate for belimumab plus standard of care, vs. placebo plus standard of care: 57.6% for 10 mg/kg belimumab, 51.7% for 1 mg/kg belimumab, and 43.6% for placebo ( $p=0.0006$  and  $p=0.011$  for 10 mg/kg and 1 mg/kg belimumab, respectively vs. placebo). Patient response was defined by an improvement in SELENA SLEDAI score of 4 points or greater, no clinically significant BILAG worsening, and no clinically significant worsening in Physician's Global Assessment.

Results for each individual component of the patient response rate were consistent with the overall improvement shown for the primary endpoint.

- Results for prespecified major secondary efficacy endpoints were:
  - A significantly greater percentage of patients receiving belimumab achieved a reduction in SELENA SLEDAI score of at least 4 points by Week 52, with 58.3% for 10 mg/kg belimumab, 53.1% for 1 mg/kg belimumab, and 46.0% for placebo ( $p=0.0024$  and  $p=0.019$  for 10 mg/kg and 1 mg/kg belimumab, respectively vs. placebo).
  - Improvement in Physician's Global Assessment (PGA) at Week 24 was greatest in the belimumab 10 mg/kg treatment group versus placebo ( $p=0.0003$  for 10 mg/kg and  $p=0.27$  for 1 mg/kg belimumab, respectively) with improvement observed within 4-8 weeks.
  - A higher percentage of patients in both belimumab treatment groups, versus placebo, had their average prednisone dose reduced by at least 25% from baseline to 7.5 mg per day or less during the last 12 weeks of study ( $p=0.053$  for 10 mg/kg and  $p=0.025$  for 1 mg/kg belimumab, respectively 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. However, although not a major secondary endpoint, improvement in the SF-36 PCS score at Week 52 was significantly greater in both belimumab treatment groups ( $p=0.025$  for 10 mg/kg and  $p=0.027$  for 1 mg/kg belimumab, respectively vs. placebo).
- In BLISS-52, belimumab was generally well tolerated, with rates of overall adverse events, serious adverse events, infections and fatalities comparable between belimumab and placebo treatment groups. Serious infections were reported in 5.9% of patients on placebo and 6.1% of patients on belimumab. The most common adverse events were headache, arthralgia, upper respiratory tract infections, urinary tract infection and influenza, and were also comparable between belimumab and placebo treatment groups. No malignancies were reported.

Professor Sandra V. Navarra, M.D., a principal investigator and Head of Rheumatology at the University of Santo Tomas, Manila, The Philippines, said, "Given the limitations of available therapies, there is a great need for well tolerated and effective treatments for lupus. We are very encouraged by the findings of BLISS-52, and look forward to presenting these results later in the year. We also look forward to the results of BLISS-76 later this year."

## About the BENLYSTA (belimumab) Phase 3 Development Program

The Phase 3 development program for belimumab includes two double-blind, placebo-controlled, multi-center 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 serologically active (i.e., autoantibody-positive) patients with SLE. This is the largest clinical trial program ever conducted in lupus patients. BLISS-52 randomized and treated 865 patients at 90 clinical sites in 13 countries, primarily in Asia, South America and Eastern Europe. BLISS-76 enrolled and randomized 826 patients at 133 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. The data from BLISS-76 will be analyzed after 52 weeks in support of a potential Biologics License Application in the United States and Marketing Authorization Application 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 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); and (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 would indicate a moderate flare of disease activity). Analysis for the primary endpoint is based on intention-to-treat (ITT) and adjusted for baseline stratification factors, including SELENA SLEDAI score, proteinuria and race.

In each of the two Phase 3 trials, patients were randomized to one of three treatment groups: 10 mg/kg belimumab (BLISS-52, n=290), 1 mg/kg belimumab (BLISS-52, n=288), or placebo (BLISS-52, n=287). Patients are dosed intravenously on Days 0, 14 and 28, then every 28 days thereafter for the duration of the study. All receive standard of care therapy in addition to the study medication. Safety is reviewed by an independent Data Monitoring Committee throughout both studies.

## 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 defense 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. BLISS 52 results suggest that belimumab can reduce SLE disease activity, and a second Phase 3 trial, BLISS-76, is underway to confirm these results.

## About the Collaboration with GSK

In August 2006, HGS and GSK entered into a definitive co-development and co-commercialization 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).

## 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 dialing 888-632-5010 or 913-312-0402, passcode 8364417, 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 dialing 888-203-1112 or 719-457-0820, confirmation code 8364417. 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

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies, and is committed 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 hepatitis C, lupus, inhalation anthrax and cancer.

The Company's primary focus is rapid progress toward the commercialization of its two lead drugs, Albuferon® (albinterferon alfa-2b) for hepatitis C and BENLYSTA™ (belimumab, formerly LymphoStat-B®) for lupus. Albuferon has now completed Phase 3 development, and the submission of global marketing applications is expected in fall 2009. BENLYSTA successfully met its primary endpoint in the first of two Phase 3 trials in systemic lupus erythematosus; results of the second BENLYSTA Phase 3 trial are expected in November 2009. Also in late-stage development is raxibacumab (ABthrax™) for the treatment of inhalation anthrax (Biologics License Application currently pending with the U.S. Food and Drug Administration). 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.

[For an Electronic Press Kit on this announcement, please click here.](#)

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## 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 the Company's unproven business model, its dependence on new technologies, the uncertainty and timing of clinical trials, the Company's 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, the Company's 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 Securities and Exchange Commission. In addition, while the Company has completed delivery of ABthrax to the U.S. Strategic National Stockpile, the Company will continue to face risks related to FDA's approval of the Company's Biologics License Application for ABthrax. If the Company is unable to meet requirements associated with the ABthrax contract, future revenues from the sale of ABthrax to the U.S. Government will not occur. 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.

## GlaxoSmithKline Forward-Looking Statements

Under the safe harbor provisions of the US 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 GSK's Annual Report on Form 20-F for 2008.

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