



## HUMAN GENOME SCIENCES ANNOUNCES SUBMISSION OF MARKETING AUTHORIZATION APPLICATION TO EMEA FOR JOULFERON® (ZALBIN™)

**ROCKVILLE, Maryland – December 15, 2009** – Human Genome Sciences, Inc. (Nasdaq: HGS1) today announced that Novartis has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for approval to market JOULFERON® (albinterferon alfa-2b, known in the United States as ZALBIN™) for the treatment of chronic hepatitis C. In November 2009, HGS submitted a Biologics License Application (BLA) for ZALBIN to the FDA in the United States.

The MAA submission includes the results of two pivotal Phase 3 clinical trials showing that 900-mcg albinterferon alfa-2b dosed every two weeks met its primary endpoint of non-inferiority to peginterferon alfa-2a (Pegasys) dosed once each week. The Phase 3 studies, known as ACHIEVE 1 and ACHIEVE 2/3, evaluated albinterferon alfa-2b vs. peginterferon alfa-2a, in combination with ribavirin, for use in the treatment of interferon-naïve patients with chronic hepatitis C. In both studies, albinterferon alfa-2b, with half the injections, achieved sustained virologic response comparable to that achieved by peginterferon alfa-2a. The rates of serious and/or severe adverse events were also comparable in these studies. ACHIEVE 1 was conducted in patients infected with genotype 1 virus, and ACHIEVE 2/3 was conducted in patients with genotypes 2 or 3 virus. The two studies treated a total of 2255 patients.

“Assuming licensure by the EMA and other regulatory agencies, HGS believes JOULFERON could become an important treatment for chronic hepatitis C,” said H. Thomas Watkins, President and Chief Executive Officer, HGS. “We look forward to continuing to work closely with Novartis to advance albinterferon alfa-2b to the market under the brand name ZALBIN in the United States.”

### About the Collaboration with Novartis

Under an exclusive worldwide co-development and commercialization agreement entered into in 2006, HGS and Novartis will co-commercialize albinterferon alfa-2b in the United States as ZALBIN™, and will share clinical development costs, U.S. commercialization costs and U.S. profits equally. Novartis will be responsible for commercialization of albinterferon alfa-2b as JOULFERON® in the rest of the world, and will pay HGS a royalty on those sales. These brand names will be subject to confirmation by health authorities at the time of product approval.

HGS has primary responsibility for the bulk manufacture of albinterferon alfa-2b, and Novartis will have responsibility for commercial manufacturing of the finished drug product. Clinical development, commercial milestone and other payments to HGS could total as much as \$507.5 million, including \$207.5 million received to date. The remaining payments to HGS under the agreement relate to the achievement of certain regulatory approval and commercial milestones.

### About ZALBIN (albinterferon alfa-2b)

ZALBIN (also known as JOULFERON) is a genetic fusion of human albumin and interferon alfa created using proprietary HGS albumin-fusion technology. Human albumin is the most prevalent naturally occurring blood protein in the human circulatory system, persisting in circulation in the body for approximately 19 days. Research has shown that genetic fusion of therapeutic proteins to human albumin decreases clearance and prolongs the half-life of the therapeutic proteins.

ZALBIN dosed once every two weeks has completed Phase 3 development. In April 2009, positive Phase 3 results of ZALBIN in patients with chronic hepatitis C were presented at the 44th annual meeting of the European Association for the Study of the Liver in Copenhagen. Data from two pivotal Phase 3 trials, ACHIEVE 1 and ACHIEVE 2/3, showed that ZALBIN met its primary endpoint of non-inferiority to Pegasys (peginterferon alfa-2a). With half the injections, ZALBIN achieved a rate of sustained virologic response comparable to Pegasys in these studies; rates of serious and/or severe adverse events were also comparable.

## About Hepatitis C

Hepatitis C is an inflammation of the liver caused by the hepatitis C virus. It is estimated that as many as 170 million people worldwide are infected with hepatitis C virus. This includes nearly four million people in the United States. When detectable levels of HCV persist in the blood for at least six months, a person is diagnosed with chronic hepatitis C. Hepatitis C virus can cause serious liver disease, leading to cirrhosis, primary liver cancer and even death. Patients infected with the genotype 1 hepatitis C virus account for approximately 75% of the chronic hepatitis C patients in the U.S.

## 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 commercialization of its two lead drugs, BENLYSTA™ (belimumab) for lupus and ZALBIN™ (albinterferon alfa-2b) for hepatitis C. Phase 3 development has been completed successfully for both BENLYSTA and Zalbin. The submission of marketing applications for BENLYSTA is planned in the U.S., Europe and other regions in the first half of 2010. A BLA has been submitted for ZALBIN to the FDA in the United States, and an MAA has been submitted under the brand name JOULFERON® to the EMEA in Europe.

In April 2009, HGS completed the delivery of 20,000 doses of raxibacumab to the U.S. Strategic National Stockpile for use in the event of an emergency to treat inhalational anthrax. In July 2009, HGS secured a new purchase order for 45,000 doses of raxibacumab to be delivered to the Stockpile over a three-year period beginning near the end of 2009. In May 2009, HGS submitted a Biologics License Application to the FDA for raxibacumab for the treatment of inhalation anthrax.

The Company also has several drugs in earlier stages of clinical development for the treatment of cancer, led by the TRAIL receptor antibody mapatumumab and a small-molecule antagonist of inhibitor-of-apoptosis proteins. 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.

## 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.

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