

## **FDA Grants Priority Review for Shire's velaglucerase alfa for Type 1 Gaucher Disease**

FDA issued action date of February 28, 2010 under the Prescription Drug User Free Act (PDUFA)

**Cambridge, MA – November 4, 2009** – Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, today announced that the United States Food and Drug Administration (FDA) has granted Priority Review for the New Drug Application (NDA) for velaglucerase alfa, the company's enzyme replacement therapy in development for the treatment of Type 1 Gaucher disease.

Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists, and accelerates the target review timing from ten to six months. The FDA has issued an action date for the NDA of February 28, 2010 under the Prescription Drug User Fee Act (PDUFA).

In the U.S., patients continue to be enrolled in an FDA-approved treatment protocol, under which Gaucher patients receive velaglucerase alfa prior to commercialization. Shire has also engaged with national and regional authorities outside the U.S. and patients are receiving velaglucerase alfa through pre-approval access programs. Shire confirms it is on track with its filing of the Marketing Authorization Application (MAA) in the EU for 2009.

### **Background on Gaucher disease**

Gaucher disease is an autosomal recessive disorder caused by mutations in the GBA gene which results in a deficiency of the lysosomal enzyme beta-glucocerebrosidase. This enzymatic deficiency causes an accumulation of glucocerebroside, primarily in macrophages. In this lysosomal storage disorder (LSD), clinical features are reflective of the distribution of Gaucher cells in the liver, spleen, bone marrow, skeleton, and lungs. The accumulation of glucocerebrosidase in the liver and spleen leads to organomegaly. Bone involvement results in skeletal abnormalities and deformities as well as bone pain crises. Deposits in the bone marrow and splenic sequestration lead to clinically significant anemia and thrombocytopenia.

Gaucher disease is the most prevalent lysosomal storage disorder, with an incidence of about 1 in 20,000 live births. Gaucher disease has classically been categorized into 3 clinical types. Type 1 is the most common; it is distinguished from Type 2 and Type 3 by the lack of central nervous system involvement. Type 1 Gaucher disease is characterized by variability in signs, symptoms, severity, and progression.

Velaglucerase alfa supplements or replaces beta-glucocerebrosidase, the enzyme that catalyzes the hydrolysis of glucocerebroside, reducing the amount of accumulated glucocerebroside and correcting the pathophysiology of Gaucher disease.

Shire's velaglucerase alfa program included the largest and most comprehensive set of Phase III clinical trials conducted to date for Gaucher disease. Over 100 patients at 24 sites in 10 countries around the world have participated the clinical studies. Velaglucerase alfa is made using Shire's proprietary technology, in a human cell line. The enzyme produced has the exact human amino acid sequence and has a human glycosylation pattern.

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**Notes to editors**

**SHIRE PLC**

Shire's strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit hyperactivity disorder (ADHD), human genetic therapies (HGT) and gastrointestinal (GI) diseases as well as opportunities in other therapeutic areas to the extent they arise through acquisitions. Shire's in-licensing, merger and acquisition efforts are focused on products in specialist markets with strong intellectual property protection and global rights. Shire believes that a carefully selected and balanced portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results.

For further information on Shire, please visit the Company's website: [www.shire.com](http://www.shire.com).

**"SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

Statements included herein that are not historical facts are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, the Company's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of research, development, approval, reimbursement, manufacturing and commercialization of the Company's Specialty Pharmaceutical and Human Genetic Therapies products, as well as the ability to secure and integrate new products for commercialization and/or development; government regulation of the Company's products; the Company's ability to manufacture its products in sufficient quantities to meet demand; the impact of competitive therapies on the Company's products; the Company's ability to register, maintain and enforce patents and other intellectual property rights relating to its products; the Company's ability to obtain and maintain government and other third-party reimbursement for its products; and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission.