

Shire Submits European Marketing Authorization Application (MAA) for velaglucerase alfa for the Treatment of Type 1 Gaucher Disease

Committee for Medicinal Products for Human Use (CHMP) Grants Accelerated Assessment

Dublin, Ireland – 24 November 2009 – Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, today announced that it has submitted a MAA to the European Medicines Agency for velaglucerase alfa, the company's enzyme replacement therapy in development for the treatment of Type 1 Gaucher disease. This is the third marketing application for velaglucerase alfa that has been submitted, with previous submissions in the United States and Canada.

Based on a global supply shortage of the currently approved and marketed treatment for patients with Gaucher disease, and positive results from all three velaglucerase alfa Phase III trials, CHMP has accepted the company's request for an accelerated assessment of the velaglucerase alfa MAA. The MAA review is expected to begin in the December cycle. Under accelerated assessment, the review timeline of the MAA is shortened from 210 days to 150 days.

"Gaucher disease is a debilitating condition and the continuing imiglucerase supply shortage has had a significant impact on patients who have lacked an alternative supply of enzyme therapy," said Timothy Cox, M.D., Professor of Medicine at the University of Cambridge and the founder of the National Centre for the Treatment of Gaucher disease at Addenbrooke's Hospital. "Shire's partnership with health regulators and physicians to devise and implement expanded access programs for velaglucerase alfa is greatly appreciated by treating physicians and the Gaucher community at large. We welcome the news of the submission of the velaglucerase alfa MAA in Europe."

In Europe and other countries outside the U.S. patients continue to receive velaglucerase alfa through pre-approval access programs that were developed in partnership with national and regional authorities and designed specifically to address the continuing supply shortage. In the U.S., patients continue to be enrolled in an FDA-approved treatment protocol that has been open since September 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 LSD. 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 early neurological symptoms. Type 1 Gaucher disease is characterized by variability in signs, symptoms, severity, and progression.

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 in 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.

"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.