

Shire Announces European Approval of VPRIV & #174; (velaglucerase alfa) for the Treatment of Type 1 Gaucher Disease

RealWire

Cambridge, MA, US - August, 27th 2010 - Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, announced today that the European Commission has granted marketing authorisation for VPRIV® (velaglucerase alfa), a human cell line derived enzyme replacement therapy (ERT) for the long-term treatment of type 1 Gaucher disease in paediatric and adult patients. VPRIV has been authorized as an orphan medicine through the Centralised Procedure, making it available in 30 countries across Europe.

This approval was based on data from Shire's velaglucerase alfa clinical development programme which represents the largest and most comprehensive clinical data set supporting registration for an ERT for type 1 Gaucher disease. In total, over 100 Gaucher patients at 24 sites in 10 countries around the world participated in the clinical studies, all of which met their primary endpoints.

"Gaucher disease is a rare but worrying and sometimes devastating condition for patients" said Tanya Collin-Histed, Executive Director, UK Gauchers Association. "Hence it is important that this additional treatment option has now been approved for use."

"This authorisation is particularly gratifying for our specialist unit, as we participated in the global trial programme for VPRIV" said Professor Atul Mehta, Clinical Director, Lysosomal Storage Disease Unit, Royal Free Hospital London. "As a physician who has managed patients with Gauchers over many years, it is great to have the opportunity to utilise new treatments within this rare disease."

Across Europe, hundreds of type 1 Gaucher patients have been receiving velaglucerase alfa through early access programmes, developed in partnership with national authorities, Gaucher expert physicians and patient associations. Globally there are over 850 patients on velaglucerase alfa and demand continues to be strong. As a result, Shire has implemented a program to carefully monitor demand and manage requests from physicians and patients in order to ensure long-term, uninterrupted treatment with VPRIV.

"The Marketing Authorisation for VPRIV in the EU is an important milestone for Shire," said Sylvie Grégoire, President, Shire Human Genetic Therapies. "Our efforts to accelerate our manufacturing, clinical and regulatory timelines have resulted in VPRIV's approval in Europe and the US months ahead of schedule."

"Gaucher disease is a rare and often debilitating condition," said Professor Tim Cox from the Department of Medicine, University of Cambridge, and founder of the

largest U.K. Gaucher clinic at Addenbrooke's Hospital. "The European approval of VPRIV is important in that we now have an alternative, licensed therapeutic enzyme. For type 1 patients the availability of VPRIV provides further opportunities to individualise treatment options for this complex disorder."

About VPRIV

Velaglucerase alfa is made using Shire's gene-activation technology, in a human cell line. Velaglucerase alfa has the exact human amino acid sequence as the endogenous glucocerebrosidase enzyme and also has a human glycosylation pattern. The safety and efficacy of velaglucerase alfa was assessed in adults and children aged 4 years and older via a phase three program, which included Gaucher patients who switched to velaglucerase alfa after being treated with imiglucerase, as well as naïve patients, including an active comparison with imiglucerase. VPRIV was approved in the United States by the Food and Drug Administration on February 26, 2010.

Important Safety Information

The most serious adverse reactions in patients treated with VPRIV were hypersensitivity reactions.

Infusion-related reactions were the most commonly observed adverse reactions in patients treated with VPRIV in clinical studies. The most commonly observed symptoms of infusion-related reactions were: headache, dizziness, hypotension, hypertension, nausea, fatigue/asthenia, and pyrexia. Generally the infusion-related reactions were mild and, in treatment-naïve patients, onset occurred mostly during the first 6 months of treatment and tended to occur less frequently with time. Other commonly observed adverse reactions in >10% of patients were: abdominal pain, back pain, joint pain, upper respiratory tract infection, and activated partial thromboplastin time prolonged. Adverse reactions more commonly seen in paediatric patients (>10% difference) included upper respiratory tract infection, rash, activated partial thromboplastin time prolonged, and pyrexia.

In clinical trials one patient developed neutralizing antibodies.

VPRIV is not available in all countries and prescribing information may differ between countries. Please consult your local prescribing information.

About 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, and other organs. The accumulation of glucocerebrosidase in the liver and spleen leads to organomegaly. Presence of Gaucher cells in the bone marrow and spleen lead to clinically significant anemia and thrombocytopenia.

Gaucher disease is the most prevalent of the lysosomal storage disorders diseases. Gaucher disease has classically been categorized into 3 clinical types. Type 1

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Gaucher disease is characterized by variability in signs, symptoms, severity, and progression. Type 1 is the most common and is distinguished from type 2 and type 3 by the lack of early neurological symptoms

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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 [1].

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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.

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Links:

[1] <http://www.shire.com/>

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