Press Release

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Shire Announces European Approval of Manufacturing Facility for VPRIV® (velaglucerase alfa)

European Medicines Agency Approval Adds Significant Capacity for the Manufacture of Shire's Enzyme Replacement Therapies

Lexington, MA, US – February 22, 2012 – Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use has approved the production of VPRIV® (velaglucerase alfa) in its new state-of-the-art manufacturing facility at 400 Shire Way in Lexington, MA. The European Commission's decision is expected imminently.

"We welcome the news that Shire's new manufacturing facility in Lexington has received EMA approval for the production of VPRIV," said Tanya Collin-Histed of the European Gaucher Alliance. "This provides patients with greater comfort over the maintenance of supply of enzyme therapies for the treatment of Gaucher disease."

Shire now has two EMA approved facilities – Alewife, in Cambridge, MA, as well as the new Lexington facility – in which to manufacture VPRIV drug substance. This additional capacity will allow Shire to significantly increase global supply of VPRIV and provides additional manufacturing flexibility. The EMA approval is also a critical first step in releasing further capacity for the manufacturing of REPLAGAL® (agalsidase alfa) at Shire's Alewife facility. The new facility increases bioreactor capacity from 1000 to 8000L, and is the first commercially licensed facility in the world to utilize single-use bioreactor and disposable technology throughout cell culture processing to reduce manufacturing risk.

"I am delighted to announce the EMA approval of our facility. Shire has invested strategically in new manufacturing facilities and state-of-the-art technology because we recognize the critical importance of ensuring the continuity of treatment for patients with rare and life-threatening diseases," said Bill Ciambrone, Senior Vice President, Technical Operations, Shire HGT. "The EMA approval of VPRIV in this manufacturing plant, only three years after breaking ground, is a testament to the hard work and dedication of Shire employees, and represents crucial additional capacity for manufacturing our enzyme replacement therapies for Gaucher and Fabry patients."

About The 400 Shire Way Manufacturing Facility

Shire has invested over $200M in manufacturing infrastructure and technology to ensure that we maintain a reliable and consistent drug supply. In keeping with Shire's corporate sustainability commitments, this new manufacturing plant has met the requirements for Leadership in Energy and Environmental Design (LEED) Certification and will receive formal recognition from the United States Green Building Council this quarter. In addition to increasing capacity and reducing manufacturing risk, utilization of single-use technology requires approximately 80% less water and 50% less energy than a conventional manufacturing plant.

About VPRIV (velaglucerase alfa)

VPRIV is made using Shire's gene activation technology, in a human cell line. The enzyme produced has the exact human amino acid sequence as that found in the naturally occurring human enzyme.

VPRIV is used for the long-term treatment of patients with type 1 Gaucher disease.

VPRIV is approved in 38 countries globally, including the US, the European Union, and Israel and is for patients who are treatment-naïve as well as patients who have previously been treated with imiglucerase.

About REPLAGAL (agalsidase alfa)

REPLAGAL is a human form of enzyme alpha-galactosidase A (α-Gal A) manufactured in a human cell line by gene activation. 2011 marked the 15th year of clinical experience with REPLAGAL, which is now approved in 46 countries worldwide. REPLAGAL is not currently approved for commercial sale in the U.S.

REPLAGAL is the only human-cell-line-derived form of enzyme replacement therapy that is indicated for the long-term treatment of patients with a confirmed diagnosis of Fabry disease (α-Gal A deficiency).

VPRIV Important Safety Information

The most serious adverse reactions seen 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, low or high blood pressure, nausea, tiredness and weakness, and fever. 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.

All adult side effects of VPRIV are considered relevant to children (ages 4 to 17 years). Side effects more commonly seen in children compared with adult patients included: upper respiratory tract infection, rash, aPTT prolonged, and fever. The safety of VPRIV has not been established in patients younger than 4 years of age.

VPRIV is not available in all countries and prescribing information may differ between countries. Please consult your local prescribing information. Full prescribing information for VPRIV in the U.S. can be found at www.VPRIV.com.

REPLAGAL Important Safety Information

The most serious adverse reactions seen with REPLAGAL were hypersensitivity reactions. Infusion-related reactions were the most commonly observed adverse reactions in patients treated with REPLAGAL in clinical studies. Most side effects are mild to moderate and include headache, tingling, numbness, tremors, fatigue, change in temperature sensation, increased blood pressure, upset stomach, diarrhea, coughing, sore throat, difficulty sleeping, change in the taste of food, change in smell, difficulty speaking, acne, dry skin and eye problems. About 1 out of 10 patients may have a reaction during or shortly after infusion of REPLAGAL. These effects include chills and facial flushing (warmth and redness).

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

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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; regenerative medicine 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 including the SmPC, 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, Shire'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 Shire's Specialty Pharmaceuticals, Human Genetic Therapies and Regenerative Medicine products, as well as the ability to secure new products for commercialization and/or development; government regulation of Shire's products; Shire's ability to manufacture its products in sufficient quantities to meet demand; the impact of competitive therapies on Shire's products; Shire's ability to register, maintain and enforce patents and other intellectual property rights relating to its products; Shire'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 Shire's filings with the Securities and Exchange Commission

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