



Shire's VPRIV[®] Wins First Ever "Novel Treatment Award" from Lysosomal Disease Network at their 9th WORLD Symposium

Lexington, MA, US – February 19, 2013 – Shire plc (LSE: SHP, NASDAQ: SHPG), announces that the Lysosomal Disease Network (LDN) presented Shire Human Genetic Therapies (HGT) with the first ever Novel Treatment Award for VPRIV on February 14th, at its 9th Annual WORLD Symposium. The LDN have launched this new award, which will be presented annually, to recognize new drugs or therapies that have made a considerable contribution in the area of lysosomal diseases.

"Shire has demonstrated its commitment to developing new therapies for the treatment of rare genetic diseases. We wanted to recognize the contribution of VPRIV for the treatment of type 1 Gaucher disease by awarding Shire the first ever Novel Treatment Award," said Chester Whitley, University of Minnesota and Principal Investigator, LDN. "As new treatments are developed, we want to be sure that these huge efforts and accomplishments are recognized in the hope of inspiring other young investigators and corporate developers. We hope that this award is a way of demonstrating this."

VPRIV is an enzyme replacement therapy (ERT) used for the long-term treatment of patients with type 1 Gaucher disease. The safety and efficacy of VPRIV was assessed in more than 100 patients at 24 sites in 10 countries, representing the largest and most comprehensive clinical data set to support registration for an ERT for type 1 Gaucher disease. VPRIV is manufactured using a human cell line with Shire's proprietary gene activation technology.

"As a leader in rare diseases, Shire is honored to be recognized by LDN with its first Novel Treatment Award," said Dr. Philip J. Vickers, Global Head of Research and Development, Shire HGT. "This award embodies the spirit of our organization – every employee at Shire is dedicated to developing and bringing forward new products, services and support offerings which can make a positive impact on patients' lives. Shire is proud to provide Gaucher patients with an effective treatment option and continues to build upon a solid foundation, established by our lysosomal enzyme replacement therapies, to further support rare disease patients around the world."

As part of its ongoing commitment in type 1 Gaucher disease, Shire continues to invest in further evaluating the safety and efficacy of VPRIV through the generation of long-term clinical trial data, additional pediatric data, as well as the long-term observational data collected through the Gaucher Outcomes Survey.

About VPRIV (velaglucerase alfa)

VPRIV is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for longterm enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease.

VPRIV has the exact human amino acid sequence as that found in the naturally occurring human enzyme.

From September 2009, patients were able to receive VPRIV via expanded access mechanisms. In parallel, Shire worked in cooperation with regulatory agencies to expedite the new drug application submissions and with priority reviews, marketing authorization of VPRIV was granted by the US FDA on 26 February 2010, 18 months ahead of anticipated timelines, and by the European Commission on 20 August 2010.

VPRIV is approved in 40 countries globally, including the US, the European Union member states, and Israel, and is for patients previously treated for type 1 Gaucher disease or those who are treatment-naive.

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 infusionrelated 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 <u>www.VPRIV.com</u>.

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NOTES TO EDITORS

Shire enables people with life-altering conditions to lead better lives.

Through our deep understanding of patients' needs, we develop and provide healthcare in the areas of:

- Behavioral Health and Gastro Intestinal conditions
- Rare Diseases
- Regenerative Medicine

as well as other symptomatic conditions treated by specialist physicians.

We aspire to imagine and lead the future of healthcare, creating value for patients, physicians, policymakers, payors and our shareholders.

www.shire.com

FORWARD - LOOKING STATEMENTS - "SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Statements included in this announcement that are not historical facts are forward-looking statements. 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, that:

- Shire's products may not be a commercial success;
- revenues from ADDERALL XR are subject to generic erosion;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payors in a timely manner for Shire's products may impact future revenues and earnings;
- Shire relies on a single source for manufacture of certain of its products and a disruption to the supply chain for those products may result in Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis;
- Shire uses third party manufacturers to manufacture many of its products and is reliant upon third party contractors for certain goods and services, and any inability of these third party manufacturers to manufacture products, or any failure of these third party contractors to provide these goods and services, in each case in accordance with its respective contractual obligations, could adversely affect Shire's ability to manage its manufacturing processes or to operate its business;
- the development, approval and manufacturing of Shire's products is subject to extensive oversight by various regulatory agencies and regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the actions of certain customers could affect Shire 's ability to sell or market products profitably and fluctuations in buying or distribution patterns by such customers could adversely impact Shire's revenues, financial conditions or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies
 relating to Shire's activities in the highly regulated markets in which it operates may result in the
 distraction of senior management, significant legal costs and the payment of substantial
 compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire's ability to obtain, maintain, enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on Shire's revenues, financial condition or results of operations;

and other risks and uncertainties detailed from time to time in Shire's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K.