

# Press Release



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## European Authorities Approve New Manufacturing Facility for Shire's REPLAGAL<sup>®</sup> (agalsidase alfa)

**DUBLIN, Ireland – June 23, 2011** – Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, today announced that the European Medicines Agency has approved the purification of REPLAGAL<sup>®</sup> (agalsidase alfa) drug substance at its new manufacturing facility in Lexington, MA, US. REPLAGAL, Shire's enzyme replacement therapy for the treatment of Fabry disease is the first product that will be made available to patients from the new facility.

With this approval, the company now has two approved facilities – Alewife, which is located in Cambridge, MA, as well as the new Lexington facility – in which to purify REPLAGAL, thus providing increased manufacturing flexibility. The cell culture portion of the REPLAGAL manufacturing process will continue to be conducted at Alewife.

"We are pleased that we were able to accelerate the construction and approval of our new manufacturing facility in order to provide rapid access to important therapies for patients in need," said Bill Ciambrone, Senior Vice President of Technical Operations, Shire HGT. "This new facility allows greater flexibility to meet global demand for our products, including REPLAGAL."

Shire reiterated that it has sufficient product inventory to continue to meet the needs of Fabry patients worldwide currently receiving REPLAGAL and that it can meet anticipated additional demand. The Company is committed to continuing to provide uninterrupted long-term access to the product at the licensed dose.

In addition to REPLAGAL, Shire anticipates regulatory agency submission of the VPRIV (velaglucerase alfa) manufacturing process at the new Lexington manufacturing facility by the end of 2011.

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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.

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