

## Press Release

### Shire files idursulfase with EMEA for treatment of Hunter syndrome

**Basingstoke, UK and Philadelphia, PA, US, – December 1, 2005** -- Shire plc (LSE: SHP, NASDAQ: SHPGY, TSX: SHQ) announced today that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for idursulfase for the treatment of Hunter syndrome. Review of a MAA by EMA typically takes 12 months. If approved, this would be the first human enzyme replacement therapy for the treatment of Hunter syndrome, also known as Mucopolysaccharidosis II (MPS II).

“Following last week’s filing in the United States, our MAA filing with the EMA is another key milestone in bringing to market a treatment for patients and families around the world living with Hunter syndrome,” said Dr. David D. Pendergast, executive vice president and general manager of Shire Human Genetic Therapies, the Shire specialty unit focused specifically on genetic diseases. “I look forward to approval and subsequent launch in Europe in late 2006 or early 2007.”

As previously announced, Shire filed idursulfase under the tradename ELAPRASE™ with the U.S. Food and Drug Administration (FDA) on November 23, 2005 under a Fast Track designation and has requested Priority Review of that submission, which would result in a six-month FDA review.

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#### Notes to editors

#### About Hunter Syndrome and idursulfase

Hunter syndrome, also known as Mucopolysaccharidosis II (MPS II), is a rare, life threatening, genetic disorder with no available treatment. Individuals with Hunter syndrome lack the enzyme iduronate-2-sulfatase, which is essential in the continuous process of replacing and breaking down glycosaminoglycans (GAG). As a result, GAG remains stored in cells in the body causing progressive damage. The symptoms of Hunter syndrome are usually not visible at birth, but usually start to become noticeable after the first or second year of life. Often the first symptoms may include hernias, frequent ear infections, runny noses, reduced growth rate and abnormal facial appearance.

As the disease progresses, a variety of symptoms appear including enlarged liver and spleen, heart failure, decreased endurance, obstructive and restrictive airway disease, sleep apnea, joint stiffness, and, in some cases, central nervous system involvement. If central nervous system involvement exists, the life expectancy for patients with Hunter syndrome is typically 10-15 years of age, however, some patients can survive into the fifth or sixth decade of life. There is currently no effective therapy for Hunter syndrome.

Idursulfase is a human iduronate-2-sulfatase produced by genetic engineering technology, developed to replace the missing enzyme in Hunter syndrome patients. Idursulfase has been designated an orphan drug in both the United States and in the European Union.

Shire believes there are approximately 2,000 patients worldwide afflicted with Hunter syndrome in countries where reimbursement may be possible.

Shire is committed to helping patients and families with Hunter syndrome. Further information about Hunter syndrome is available at <http://www.hunterpatients.com>.

## **SHIRE PLC**

Shire's strategic goal is to become the leading specialty pharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on central nervous system, gastrointestinal, general products and human genetic therapies - all being areas in which Shire has a commercial presence. The structure is sufficiently flexible to allow Shire to target new therapeutic areas to the extent opportunities arise through acquisitions. Shire believes that a carefully selected portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results. Shire's strategy is to develop and market products for specialty physicians. Shire's in-licensing and merger and acquisition efforts are focused on products in niche markets with strong intellectual property protection either in the US or Europe.

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 forwarding-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 plc's results could be materially affected. The risks and uncertainties include, but are not limited to; risks associated with the inherent uncertainty of pharmaceutical research, product development, manufacturing and commercialization; the impact of competitive products, including, but not limited to, the impact of those on Shire plc's Attention Deficit and Hyperactivity Disorder ("ADHD") franchise; patents, including but not limited to, legal challenges relating to Shire plc's ADHD franchise; government regulation and approval, including but not limited to the expected product approval dates of DAYTRANA<sup>™</sup> (MTS/METHYPATCH) (ADHD), SPD503 (ADHD), SPD465 (ADHD), MESAVANCE<sup>™</sup> (SPD476) (ulcerative colitis), ELAPRASE<sup>™</sup> (idursulfase) (Hunter syndrome) and NRP104 (ADHD), including its scheduling classification by the Drug Enforcement Administration in the United States; Shire plc's ability to benefit from the acquisition of Transkaryotic Therapies Inc.; Shire plc's ability to secure new products for commercialization and/or development; and other risks and uncertainties detailed from time to time in Shire plc's and its predecessor registrant Shire Pharmaceuticals Group plc's filings with the US Securities and Exchange Commission, including Shire Pharmaceuticals Group plc's Annual Report on Form 10-K for the year ended December 31, 2004.

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