

District Court Upholds FDA's Grant of 5-Year Market Exclusivity to VYVANSE®

Philadelphia, US – March 4, 2010 –Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, announces that the United States District Court for the District of Columbia (“Court”), following extensive briefing by the parties and an oral hearing, has upheld the decision of the U.S. Food and Drug Administration (“FDA”) to grant 5-year New Chemical Entity (“NCE”) exclusivity to lisdexamfetamine dimesylate—currently marketed by Shire U.S. Inc. for the treatment of attention-deficit hyperactivity disorder under the name VYVANSE®.

On February 23, 2007, after reviewing the requisite clinical studies submitted on behalf of VYVANSE, the FDA determined that VYVANSE qualified as an NCE within the meaning of the governing statutes and regulations. As an NCE, VYVANSE is entitled to 5-year market exclusivity. The FDA therefore appropriately refused to file the Abbreviated New Drug Application (“ANDA”) submitted by Actavis Elizabeth, LLC for generic lisdexamfetamine dimesylate. On February 24, 2009, Actavis sued the FDA in the District Court of the District of Columbia challenging the NCE decision. On April 13, 2009, the FDA opened a public docket to consider Actavis’s challenge to the FDA’s regulations governing NCE exclusivity and the corresponding award of exclusivity to VYVANSE. On October 23, 2009, following a thorough administrative review, the agency affirmed lisdexamfetamine, the active ingredient in VYVANSE, is a new active moiety and that its prior designation of VYVANSE as an NCE was proper.

Shire is pleased that on March 4, 2010, following the extensive briefing of the parties and an oral hearing, the Court upheld the FDA’s decision (and reaffirmation) that VYVANSE is entitled to 5-year market exclusivity. The Court correctly determined that FDA’s actions complied with federal administrative law standards as a reasonable exercise of the agency’s scientific expertise. The five-year exclusivity period for VYVANSE expires on February 23, 2012, and precludes generic manufacturers from submitting an ANDA to FDA until that time, or until February 23, 2011 should a generic applicant challenge the United States patents covering Vyvanse, which remain in effect until June 29, 2023.

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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.

"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.