Press Release



www.shire.com

U.S. Supreme Court Grants Shire Petition

LIALDA Patent Case Sent Back to Federal Circuit

Lexington, Mass. – January 27, 2015 – Shire plc (LSE: SHP, NASDAQ: SHPG) today announced that the U.S. Supreme Court granted Shire's petition in the *Shire v. Watson* patent case regarding LIALDA® (mesalamine, 1.2 gram). The granting of this petition by the Supreme Court vacates the decision of the U.S. Court of Appeals for the Federal Circuit with respect to the claim construction in the case against Watson (now Actavis).

In 2013, Shire prevailed in the United States District Court for the Southern District of Florida in a patent litigation against Watson (now Actavis) involving U.S. Patent No. 6,773,720 for LIALDA. On appeal, the Federal Circuit reversed the District Court's claim construction. With the granting of the petition by the Supreme Court, the Federal Circuit's decision on claim construction is vacated, and the case will be remanded back to the Federal Circuit for further consideration under the deferential standard of review announced by the Supreme Court last week in *Teva v. Sandoz*.

Shire is pleased with the Supreme Court's recent action and believes that it substantiates Shire's continued confidence in its patent position.

For further information please contact:

Investor Relations

Sarah Elton-Farr <u>seltonfarr@shire.com</u> +44 1256 894157

Media

Gwen Fisher <u>afisher@shire.com</u> +1 484 595 9836

NOTES TO EDITORS

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

Our strategy is to focus on developing and marketing innovative specialty medicines to meet significant unmet patient needs.

We focus on providing treatments in Rare Diseases, Neuroscience, Gastrointestinal, and Internal Medicine and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas, such as Ophthalmics.

www.shire.com

SHIRE FORWARD-LOOKING STATEMENTS

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, that:

- Shire's products may not be a commercial success;
- revenues from ADDERALL XR and INTUNIV 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, financial condition and results of operations;
- Shire conducts its own manufacturing operations for certain of its products and is reliant on third party contract manufacturers to manufacture other products and to provide goods and services. Some of Shire's products or ingredients are only available from a single approved source for manufacture. Any disruption to the supply chain for any of Shire's 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 for some period of time;
- the development, approval and manufacturing of Shire's products is subject to extensive oversight by various regulatory agencies. Submission of an application for regulatory approval of any of our product candidates, such as our planned submission of a New Drug Application to the FDA for Lifitegrast, may be delayed for any number of reasons and, once submitted, may be subjected to lengthy review and ultimately rejected. Moreover, 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. Fluctuations in buying or distribution patterns by such customers can adversely impact Shire's revenues, financial condition 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 significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire's ability to 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;
- Shire faces intense competition for highly qualified personnel from other companies, academic institutions, government entities and other organizations. Shire is undergoing a corporate reorganization and the consequent uncertainty could adversely impact Shire's ability to attract and/or retain the highly skilled personnel needed for Shire to meet its strategic objectives;
- failure to achieve Shire's strategic objectives with respect to the acquisition of ViroPharma Incorporated may adversely affect Shire's financial condition and results of operations;
- Shire's proposed acquisition of NPS Pharma may not be consummated due to the
 occurrence of an event, change or other circumstances that gives rise to the
 termination of the merger agreement;
- a governmental or regulatory approval required for the proposed acquisition of NPS
 Pharma may not obtained, or may be obtained subject to conditions that are not
 anticipated, or another condition to the closing of the proposed acquisition may not be
 satisfied;
- NPS Pharma may be unable to retain and hire key personnel and/or maintain its relationships with customers, suppliers and other business partners pending the consummation of the proposed acquisition by Shire, or NPS Pharma's business may

- be disrupted by the proposed acquisition, including increased costs and diversion of management time and resources;
- difficulties in integrating NPS Pharma into Shire may lead to the combined company not being able to realize the expected operating efficiencies, cost savings, revenue enhancements, synergies or other benefits at the time anticipated or at all;

and other risks and uncertainties detailed from time to time in Shire's or NPS Pharma's filings with the Securities and Exchange Commission, including their respective most recent Annual Reports on Form 10-K.