

## Shire Wins Patent Trial Against Watson concerning LIALDA<sup>®</sup>

**Philadelphia, PA, USA – May 9, 2013** – Shire plc (LSE: SHP, NASDAQ: SHPG), announces that its subsidiary, Shire Development LLC, has prevailed in its litigation against Watson Pharmaceuticals Inc., Watson Laboratories, Inc.-Florida, Watson Pharma, Inc. and Watson Laboratories, Inc. (collectively “Watson”, now “Actavis”) in connection with their Abbreviated New Drug Application (“ANDA”) for a generic version of Shire’s LIALDA<sup>®</sup> (mesalamine) delayed release tablets for the induction of remission in adults with active, mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis.

Following a five day bench trial in the Southern District of Florida, Judge Middlebrooks issued a ruling upholding the validity of the patent covering LIALDA, US Patent No. 6,773,720 (the “’720 patent”), and holding that the proposed ANDA formulation infringes the claims of that patent. Accordingly, Judge Middlebrooks confirmed that Shire is entitled to an injunction, which he will issue separately, which prohibits the FDA from approving the ANDA formulation until the expiration of the ‘720 patent.

“Shire is very pleased that the court has ruled in our favor. We rely on our patents to be able to continue to invest in therapies that bring value to our patients and their caregivers. This ruling supports the innovative therapies that we develop in order to improve the lives of ulcerative colitis patients.” stated Roger Adsett, head of Shire’s GI Business Unit.

Shire’s LIALDA remains the only once-daily mesalamine product indicated for both the induction of remission of mild to moderate ulcerative colitis and for the maintenance of remission of ulcerative colitis. No ANDA’s have been approved for generic versions of LIALDA.

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## 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 provide treatments in Neuroscience, Rare Diseases, Gastrointestinal, Internal Medicine and Regenerative Medicine and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas.

[www.shire.com](http://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.