

## Shire Wins Patent Trial against Watson Concerning LIALDA®

*LIALDA Patent Upheld and Extends through June 8, 2020*

**[Lexington, MA] – [March 29, 2016]** – Shire plc (LSE: SHP, NASDAQ: SHPG) and its subsidiary, Shire Development LLC, announced today that the United States District Court for Southern Florida has upheld its patent for LIALDA® (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.

The decision follows litigation by Shire 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 LIALDA.

Judge Donald M. Middlebrooks issued a ruling holding that Actavis’ proposed ANDA formulation infringes US Patent No. 6,773,720 (“’720 patent”), the Orange Book listed patent for LIALDA, which extends through June 8, 2020. Accordingly, Judge Middlebrooks entered an injunction prohibiting the FDA from approving the ANDA formulation until the expiration of the ’720 patent and an injunction against Actavis prohibiting them from making, using, selling or importing their proposed ANDA product until after the expiration of the ’720 patent. This is the second patent infringement trial in which the proposed ANDA product from Actavis (formerly Watson) has been found to infringe the ’720 patent.

“Shire is very pleased that the court has once again ruled in our favour, reaffirming the validity of the patent protecting LIALDA,” said James Harrington, Senior Vice President, Global Head of Intellectual Property, Shire. “This ruling supports the innovation and value we continue to bring to the patients who benefit from this important medicine that allows them to lead better lives.”

Shire’s LIALDA remains the only once-daily mesalamine product indicated for both the induction of remission of mild to moderate ulcerative colitis and the maintenance of remission of ulcerative colitis.

### Indication

Lialda is a prescription medication approved for the induction of remission in patients with active, mild to moderate ulcerative colitis (UC) and for the maintenance of remission of UC.

### Important Safety Information

Do not take Lialda (mesalamine) if you are allergic to salicylates, such as aspirin, or medications that contain aspirin; aminosaliclates; mesalamine; or any other ingredients in Lialda.

Tell your doctor if you:

- have or have had kidney problems. Kidney problems have been reported with medications that contain mesalamine, such as Lialda. Your doctor may check to see how your kidneys are working before starting Lialda and periodically while taking Lialda.
- have symptoms including cramping, stomach ache, bloody diarrhea, fever, headache, and rash. Medications that contain mesalamine, such as Lialda, have been associated

with a condition that may be hard to tell apart from a UC flare. Call your doctor right away if you have any of these symptoms. He or she may tell you to stop taking Lialda.

- are allergic to sulfasalazine, as you may also be allergic to Lialda or medications that contain mesalamine.
- have or have had heart-related allergic reactions, such as inflammation of the heart muscle (myocarditis) or the lining of the heart (pericarditis). These reactions have been seen in patients taking Lialda or medications that contain mesalamine. Your chance of having these types of reactions may increase when taking Lialda.
- have or have had liver problems. Problems with liver function have been reported in patients who have or have had liver problems and were taking medications that contain mesalamine, such as Lialda.
- have a stomach blockage. It may take longer for Lialda to start working.

The most common side effects reported in clinical studies of Lialda were:

- ulcerative colitis
- headache
- passing gas
- abnormal liver function test results
- stomach ache

In clinical studies of Lialda, inflammation of the pancreas also occurred. If this happens to you, your doctor may tell you to stop taking Lialda.

Other side effects may occur.

Before starting Lialda, tell your doctor about all medications you are taking, including:

- non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen. Taking these medications with Lialda may increase your chance of kidney problems.
- azathioprine and 6-mercaptopurine. Taking these medications with Lialda may increase your chance of blood disorders.

**Please see [Full Prescribing Information](#) for Lialda (mesalamine)**

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch), or call 1-800-FDA-1088.

**For further information please contact:**

**Investor Relations**

Sarah Elton-Farr	<a href="mailto:seltonfarr@shire.com">seltonfarr@shire.com</a>	+44 1256 894157
Robert Coates	<a href="mailto:rcoates@shire.com">rcoates@shire.com</a>	+44 1256 894874

**Media**

Michele Galen	<a href="mailto:mgalen@shire.com">mgalen@shire.com</a>	+1 781 482 1867
Gwen Fisher	<a href="mailto:gfisher@shire.com">gfisher@shire.com</a>	+1 484 595 9836
Brooke Clarke	<a href="mailto:brclarke@shire.com">brclarke@shire.com</a>	+44 1256 894829

## **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](http://www.shire.com)

## Forward-Looking Statements

Statements included herein that are not historical facts, including without limitation statements concerning our announced business combination with Baxalta and the timing and financial and strategic benefits thereof, our 20x20 ambition that targets \$20 billion in combined product sales by 2020, as well as other targets for future financial results, capital structure, performance and sustainability of the combined company, the combined company's future strategy, plans, objectives, expectations and intentions, the anticipated timing of clinical trials and approvals for, and the commercial potential of, inline or pipeline products 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, the following:

- the proposed combination with Baxalta may not be completed due to a failure to satisfy certain closing conditions, including any shareholder or regulatory approvals or the receipt of applicable tax opinions;
- disruption from the proposed transaction with Baxalta may make it more difficult to conduct business as usual or maintain relationships with patients, physicians, employees or suppliers;
- the combined company may not achieve some or all of the anticipated benefits of Baxalta's spin-off from Baxter International, Inc. ("Baxter") and the proposed transaction may have an adverse impact on Baxalta's existing arrangements with Baxter, including those related to transition, manufacturing and supply services and tax matters;
- the failure to achieve the strategic objectives with respect to the proposed combination with Baxalta may adversely affect the combined company's financial condition and results of operations;
- products and product candidates may not achieve commercial success;
- product sales from ADDERALL XR and INTUNIV are subject to generic competition;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payers in a timely manner for the combined company's products may affect future revenues, financial condition and results of operations, particularly if there is pressure on pricing of products to treat rare diseases;
- supply chain or manufacturing disruptions may result in declines in revenue for affected products and commercial traction from competitors; regulatory actions associated with product approvals or changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, an increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the successful development of products in various stages of research and development is highly uncertain and requires significant expenditures and time, and there is no guarantee that these products will receive regulatory approval;
- the actions of certain customers could affect the combined company's ability to sell or market products profitably, and fluctuations in buying or distribution patterns by such customers can adversely affect the combined company's revenues, financial condition or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to the combined company'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 the combined company's ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on the combined company's revenues, financial condition or results of operations;
- Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect the combined company's ability to attract and/or retain the highly skilled personnel needed to meet its strategic objectives;
- failure to achieve the strategic objectives with respect to Shire's acquisition of NPS Pharmaceuticals Inc. or Dyax may adversely affect the combined company's financial condition and results of operations;
- the combined company will be dependent on information technology and its systems and infrastructure face certain risks, including from service disruptions, the loss of sensitive or confidential information, cyber-attacks and other security breaches or data leakages that could have a material adverse effect on the combined company's revenues, financial condition or results of operations;
- the combined company may be unable to retain and hire key personnel and/or maintain its relationships with customers, suppliers and other business partners;
- difficulties in integrating Dyax or Baxalta 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, Dyax's or Baxalta's filings with the Securities and Exchange Commission ("SEC"), including those risks outlined in Baxalta's current

Registration Statement on Form S-1, as amended, and in “ITEM 1A: Risk Factors” in Shire’s Annual Report on Form 10-K for the year ended December 31, 2015.

All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Except to the extent otherwise required by applicable law, we do not undertake any obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.