



# Shire Settles Patent Infringement Lawsuit Against Teva concerning INTUNIV<sup>®</sup>

**Philadelphia**, **PA**, **USA** – **May 31**, **2013** – Shire LLC has settled its litigation against Teva Pharmaceuticals USA Inc. ("Teva") in connection with Teva's Abbreviated New Drug Application ("ANDA") for a generic version of Shire's INTUNIV (guanfacince) Extended Release Tablets for the treatment of Attention Deficit Hyperactivity Disorder.

The settlement provides Teva with a license to market in the United States either its own generic versions of INTUNIV or authorized generic versions of INTUNIV supplied by Shire. The license takes effect after the expiration of the 180 day exclusivity period granted to Actavis, as the first ANDA filer. Actavis is licensed by Shire to market generic product beginning on December 1, 2014.

The litigation involves a patent infringement lawsuit relating to U.S. patents 6,287,599 ("the '599 Patent"), and 6,811,794 ("the '794 Patent"). A bench trial against Actavis and Teva was held in September 2012. As Shire has previously settled with Actavis, and has now settled with Teva, the court will not be issuing a decision on the trial. As part of the settlement, Teva has confirmed that its proposed generic products infringe Shire's '599 and '794 Patents and that the two patents are valid and enforceable with respect to those proposed generic products.

The agreements, which are effective immediately, have been submitted to the US Federal Trade Commission for its review as required by law.

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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

## 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 ADDE RALL 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.