Press Release

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Shire Provides Regulatory Update on SHP 465, Investigational Compound for ADHD in Adults

October 9, 2014 – Shire plc (LSE: SHP, NASDAQ: SHPG) today announced that it has received further guidance from the U.S. Food and Drug Administration (FDA) on the regulatory path for SHP 465 (triple-bead mixed amphetamine salts MAS), an investigational oral stimulant medication being evaluated as a potential treatment for Attention-Deficit/Hyperactivity Disorder (ADHD) in adults. On April 25, 2014, in written correspondence, the FDA responded to Shire's resubmission proposal package confirming that Shire could submit SHP 465 as a Class 2 resubmission. After a series of follow-up discussions, the FDA has now clarified that additional pediatric data would be required for resubmission of SHP 465. This information will impact Shire's plans for a 2014 New Drug Application (NDA) resubmission for SHP 465.

SHP 465 has the potential to be an important treatment option for adults with ADHD, and Shire is engaging with the FDA to define the clinical data requirements.

ABOUT ADHD IN ADULTS

Attention-Deficit/Hyperactivity Disorder is a neurobehavioral disorder that manifests as a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development and is inconsistent with developmental level.

An estimated 4.4% of adults met *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, (DSM-4®) criteria for ADHD in the US based on clinical interview. When extrapolated to the full US adult population aged 18 and over, approximately 10.5 million adults were estimated to have ADHD in the US.

The specific etiology of ADHD is unknown. The diagnosis is made utilizing criteria specified in the DSM-5 or International Classification of Diseases, 10th revision (ICD-10). Only a trained health care professional can evaluate and diagnose ADHD.

Although there is no cure for ADHD, there are accepted treatments that have been demonstrated to improve symptoms. Standard treatments include educational approaches, psychological therapies which may include behavioral modification, and/or medication. Ongoing assessment and treatment may be necessary.

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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, and Internal Medicine, and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas, such as Ophthalmology.

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THE "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, 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 and revenues from INTUNIV will become subject to generic competition starting in December 2014;
- 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 Rare Diseases 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;

- the recommended combination with AbbVie Inc. (" AbbVie") is subject to a number of conditions, including approval by shareholders and regulators

and other risks and uncertainties detailed from time to time in Shire's filings with the Securities and Exchange Commission, including those risks outlined in "Item 1A: Risk Factors" in Shire's Annual Report on Form 10-K for the year ended December 31, 2013.