Press Release

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For Release to US Media Only

Positive response from European Decentralised Procedure for Elvanse Adult®▼ (lisdexamfetamine dimesylate) in adults with ADHD

Lexington, Mass. – January 22, 2015 – Shire plc (LSE: SHP, NASDAQ: SHPG) today announces the positive response from the European Decentralised Procedure (DCP) for Elvanse Adult® in the three European countries participating in the procedure (UK, Denmark and Sweden).

Elvanse Adult was accepted for review by the UK Medicines and Healthcare products Regulatory Agency (MHRA) in February 2014. The application was based on four Phase 3 studies designed to assess the efficacy and safety of Elvanse Adult in adults with ADHD.

The UK MHRA acted as the Reference Member State on behalf of the three European countries. Product labelling has been agreed by these countries, which will now issue their national Marketing Authorisations (approvals). This typically takes one to three months, however, the timing for this process varies among countries.

"We are delighted to be so close to the first European approvals of Elvanse Adult, for the UK, Denmark and Sweden," said Dr. Philip J. Vickers, Global Head of Research and Development, Shire. "In Europe, the choice of licensed medications for diagnosed adults with ADHD is currently limited. After receipt of regulatory approval, we will work closely with the respective countries to ensure that Elvanse Adult is made available to patients as soon as possible."

About lisdexamfetamine dimesylate

Lisdexamfetamine dimesylate is available for children six years of age and over, adolescents and adults in the USA and Canada (brand name Vyvanse) and in Brazil (brand name Venvanse).

In addition, lisdexamfetamine dimesylate is currently available in eight European countries indicated as part of a comprehensive treatment programme for ADHD in children and adolescents 6 years of age and over when response to previous methylphenidate treatment is considered clinically inadequate (brand names Elvanse®▼ /Tyvense®▼).

CNS stimulants (amphetamines and methylphenidate-containing products) have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

About Adult ADHD

ADHD is a common psychiatric disorder in children, adolescents and adults. While commonly thought of as a childhood condition, nearly 50% of children with ADHD may continue to meet the criteria for the disorder in adulthood, based on parent report. Worldwide, 3.4% (range 1.2-7.3%) of adults aged 18-44 are thought to have ADHD based on the World Health Organization World Mental Health Survey Initiative.

About the Elvanse Adult Indication

Elvanse Adult is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) in adult patients.

Elvanse Adult is not indicated in all adult patients and the decision to use the medicinal product must take into consideration the profile of the patient, including a thorough medical history assessment of the severity and chronicity of the patient's symptoms, the potential for abuse, misuse or diversion and clinical response to any previous pharmacotherapies for the treatment of ADHD.

About Vyvanse® (lisdexamfetamine dimesylate) – U.S.

Information about Vyvanse

Vyvanse is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep in a safe place to prevent misuse and abuse. Selling or sharing Vyvanse may harm others and is illegal.

Vyvanse is indicated for the treatment Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 years and above. Vyvanse capsules are currently available in seven dosage strengths of 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg.

ADDITIONAL IMPORTANT SAFETY INFORMATION

- **Do not take Vyvanse if you or your child:**
  - is taking or has taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI
  - is sensitive to, allergic to, or had a reaction to other stimulant medicines

- **Some people have had the following problems when taking stimulant medicines, such as Vyvanse:**

  1. Heart-related problems including:
  - **sudden death in people who have heart problems or heart defects**
  - **sudden death, stroke and heart attack in adults**
  - **increased blood pressure and heart rate**

  Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems. The doctor should check your or your child's blood pressure and heart rate regularly during treatment. **Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Vyvanse.**

  2. Mental (psychiatric) problems including:
  - **new or worse behavior and thought problems**
  - **new or worse bipolar illness**

  In Children and Teenagers
  - **new psychotic symptoms such as:**
    - **seeing things or hearing voices that are not real**
    - **believing things that are not true**
    - **being suspicious**
  - **new manic symptoms**

Tell your doctor about any drug abuse, alcohol abuse or mental problems that you or your child has had, or about a family history of suicide, bipolar illness, or depression.
Call your doctor right away if you or your child has any new or worsening mental symptoms or problems while taking Vyvanse.

3. **Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]:**
    - **Fingers or toes may feel numb, cool, painful, sensitive to temperature and/or change color from pale, to blue, to red**

    Call your doctor right away if you have or your child has any of these signs or symptoms or develops unexplained wounds on fingers or toes while taking Vyvanse.

- Tell the doctor if you or your child is pregnant, breast-feeding, or plans to become pregnant or breast-feed.

- **Vyvanse may cause serious side effects, including:**
    - slowing of growth (height and weight) in children. Your child should have his or her height and weight checked often while taking Vyvanse. The doctor may stop treatment if a problem is found during these check-ups.

- **The most common side effects reported in studies of Vyvanse were:**
    - anxiety
    - decreased appetite
    - diarrhea
    - dizziness
    - dry mouth
    - irritability
    - loss of appetite
    - nausea
    - trouble sleeping
    - upper stomach pain
    - vomiting
    - weight loss

For additional safety information, click here for Prescribing Information and Medication Guide and discuss with your doctor.

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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.

THE "SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Statements included in this communication 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 U.S. Securities and Exchange Commission, including their respective most recent Annual Reports on Form 10-K.