Press Release

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Vyvanse® Patents Found to Be Infringed and Valid by U.S. District Court

Lexington, Mass., USA - June 25, 2014 – Shire plc (LSE: SHP, NASDAQ: SHPG) announces that Judge Stanley R. Chesler of the U.S. District Court for the District of New Jersey granted Shire's summary judgment motion in a patent infringement lawsuit, holding that certain claims of the patents protecting Vyvanse® (lisdexamfetamine dimesylate) were both infringed and valid.

The ruling prevents the five pharmaceutical manufacturers (the ANDA- Defendants) who have filed Abbreviated New Drug Applications (ANDAs) from launching generic versions of Vyvanse until the earlier of either a successful appeal to the U.S. Court of Appeals for the Federal Circuit, or the expiration of these patents in 2023. To appeal successfully, the ANDA-Defendants must overturn the Court's rulings for each of the 18 patent claims.

The Court's summary judgment ruling concerning Shire's motion included 18 patent claims from four of the FDA Orange Book-listed patents for Vyvanse, which cover Vyvanse's active ingredient, the lisdexamfetamine dimesylate compound, and a method of using lisdexamfetamine dimesylate for the treatment of ADHD.

"We are extremely pleased with the Court's ruling, which affirms Shire's belief that it has strong patents protecting Vyvanse," said Flemming Ornskov, MD, Chief Executive Officer for Shire.

Shire's Vyvanse patents expire in 2023 but Shire recently announced that it has agreed to a Written Request by the Food and Drug Administration to conduct pediatric clinical studies to investigate the potential use of Vyvanse for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in preschool-age children, ages 4 to 5. Upon FDA confirmation of a timely submission and review of data that adheres to the requirements of the Written Request, Shire will be entitled to the benefits of the Best Pharmaceuticals for Children Act, including a six-month extension to the exclusivity afforded by Shire's patents for Vyvanse.

Shire's lawsuit is against the five ANDA - Defendants that filed ANDAs with the U.S. Food and Drug Administration (FDA) seeking to market generic versions of Vyvanse, and their Active Pharmaceutical Ingredient (API) manufacturer of lisdexamfetamine dimesylate API. The ANDA-Defendants are Actavis LLC/Actavis Elizabeth LLC; Amneal Pharmaceuticals, LLC; Mylan Pharmaceuticals Inc./Mylan Inc.; Roxane Laboratories Inc.; and Sandoz Inc. The API manufacturer and supplier to each of the ANDA-Defendants is Johnson Matthey Inc./Johnson Matthey Pharmaceutical Materials. This lawsuit includes all of the known ANDAs that are currently pending for Vyvanse.

The Court found that "[t]here is no real dispute about the ANDA Defendants' direct infringement of the compound claims," Johnson Matthey "is liable for inducing the ANDA Defendants' direct infringement of the compound claims," and "the ANDA Defendants have induced infringement" of a claimed method of treating ADHD. As to validity, the Court found that "Defendants have not shown that lisdexamfetamine was disclosed in the prior art" and "Defendants have failed to point to evidence sufficient to persuade a reasonable jury that [prior art reference] AU '168 anticipates by disclosing lisdexamfetamine dimesylate," and

"have failed to defeat the motion for summary judgment regarding invalidity due to obviousness of the compound patents." Additionally, the Court found that "Defendants have not offered evidence sufficient to prove [method of treating ADHD] claim 4 of the '486 patent is invalid due to obviousness or anticipation."

Shire's summary judgment motion did not include every patent claim in the litigation and, accordingly, the Court's decision did not dispose of the litigation in its entirety. In addition to Shire's motion, the Court also ruled on five summary judgment motions filed by the defendants. The Court's rulings denied API-supplier Johnson Matthey's motion to dismiss certain indirect infringement claims, dismissed Shire's willful infringement claims, granted defendants' motion concerning noninfringement of certain method of use claims, and denied defendants' two invalidity motions. At this point, the Court must decide whether to conduct a trial on the remaining patent claims, or allow the defendants to immediately appeal this ruling to the Federal Circuit. Shire maintains its belief that it has strong infringement claims against each of the six defendants for the patent claims that were not included in Shire's motion, and strongly believes that the asserted patent claims are valid.

ABOUT Vyvanse® (lisdexamfetamine dimesylate)

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 six once-daily dosage strengths of 20mg, 30mg, 40mg, 50mg, 60mg, and 70mg.

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:**
  - **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.
  - **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.
    - **Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]:**
        - **Fingers or toes may feel numb, cool, painful, sensitive**

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.

For further information please contact:

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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 focus on providing 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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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 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 contractors 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 the 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 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 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;

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.

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