## **Press Release**



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# Shire to Present New Research at American Psychiatric Association Annual Meeting

**Lexington, MA – May 11, 2015** – Shire plc (LSE: SHP, NASDAQ: SHPG) today announced that new research highlighting its commitment to the treatment and management of psychiatric disorders will be presented at the upcoming American Psychiatric Association (APA) 168<sup>th</sup> Annual Meeting in Toronto.

"These data presentations underscore Shire's long-standing heritage and dedication to advancing research into the unmet needs of patients," said Barry K. Herman, MD, MMM, DLFAPA, Global Medical Team Lead, Neuroscience Global Medical Affairs for Shire.

Posters presented on Monday, May 18 (2:00 PM EDT) will include:

- **Poster Number P6-069:** Development of the Binge Eating Disorder Screener; *Presented by Barry K. Herman MD, MMM*
- **Poster Number P7-071:** Characterization of Binge Eating Behavior in Individuals with Binge Eating Disorder in a US Adult Population; *Presented by Manjiri Pawaskar, PhD*
- Poster Number P6-010: Randomized, Double-Blind, Active- and Placebo-Controlled Trials of Lisdexamfetamine in Adolescents with Attention-Deficit/Hyperactivity Disorder; Presented by Glen Frick, MD, PhD
- Poster Number P6-004: Comparison of Quality of Life, Productivity and Functioning Between Diagnosed and Undiagnosed Adults with Attention-Deficit/Hyperactivity-Disorder; Presented by Manjiri Pawaskar, PhD
- Poster Number P6-003: Estimating the Prevalence of DSM-5 Attention-Deficit/Hyperactivity Disorder (ADHD) in a Community Sample; Presented by Manisha Madhoo, MD

Vyvanse (lisdexamfetamine dimesylate) is a prescription medicine used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 years and above and for the treatment of moderate to severe binge eating disorder (B.E.D.) in adults. Vyvanse is not for weight loss. It is not known if Vyvanse is safe and effective for the treatment of obesity.

Vyvanse is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Vyvanse in a safe place to prevent misuse and abuse. Selling or giving away Vyvanse may harm others, and is against the law.

#### About B.E.D.

Binge eating disorder, now recognized as a distinct disorder, is defined as recurring episodes (on average, at least once weekly, for 3 months) of consuming a large amount of food in a short time, compared with what others would consume under the same or similar circumstances. Patients feel a sense of lack of control during a binge eating episode and marked distress over their eating. They typically experience shame and guilt, among other symptoms, about their binge eating, and may conceal the symptoms. Unlike people with other eating disorders, adults with B.E.D. don't routinely try to "undo" their excessive eating with extreme actions like purging or over-exercising.

B.E.D. is the most common eating disorder in US adults and is more prevalent than anorexia and bulimia combined. B.E.D. occurs in both men and women, is seen across racial and ethnic groups, and can occur in normal weight, overweight, and obese adults. Medication is not appropriate for all adults with B.E.D.

#### **About ADHD**

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.

ADHD is one of the most common childhood psychiatric disorders. An estimated 11 percent (6.4 million) of US school-aged children have been diagnosed with ADHD in their lifetime, based on the 2011/12 National Survey of Children's Health, in which parents were asked if a health care practitioner had ever told them their child had ADD or ADHD. Although many people tend to think of ADHD as a childhood problem, 60% to 85% of children with ADHD may continue to meet the criteria for the disorder during their teenage years. Nearly 50% of children with ADHD may continue to meet the criteria for the disorder in adulthood, based on parent report. The disorder is estimated to affect 4.4 percent of US adults aged 18 to 44 based on results from the National Comorbidity Survey Replication. When this percentage is extrapolated to the full US population aged 18 and over, approximately 10 million adults are estimated to have ADHD. Drug treatment may not be appropriate for all patients with ADHD.

The specific etiology of ADHD is unknown. The diagnosis is made utilizing criteria specified in the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition, (*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.

#### **About VYVANSE®** (lisdexamfetamine dimesylate)

#### What is Vyvanse?

Vyvanse is a prescription medicine used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 years and above, and for the treatment of moderate to severe binge eating disorder (B.E.D.) in adults. Vyvanse is not for weight loss. It is not known if Vyvanse is safe and effective for the treatment of obesity.

#### IMPORTANT SAFETY INFORMATION

Vyvanse is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Vyvanse in a safe place to prevent misuse and abuse. Selling or giving away Vyvanse may harm others, and is against the law.

Vyvanse is a stimulant medicine. Tell the doctor if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

#### Who should not take Vyvanse?

#### Do not take Vyvanse if you or your child is:

- taking or has taken an anti-depression medicine called a monoamine oxidase inhibitor (MAOI) within the past 14 days.
- sensitive or allergic to, or had a reaction to other stimulant medicines.

#### Problems that can occur while taking Vyvanse (lisdexamfetamine dimesylate). Tell the doctor:

- if you or your child have heart problems or heart defects, high blood pressure, or a family history of these problems. This is important because sudden death has occurred in people with heart problems or defects, and sudden death, stroke and heart attack have happened in adults. Since increases in blood pressure and heart rate may occur. the doctor should regularly check these during treatment. Call the doctor right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Vyvanse.
- if you or your child have mental problems, or a family history of suicide, bipolar illness, or depression. This is important because new or worsening behavior and thought problems or bipolar illness may occur. New symptoms such as seeing or hearing things that are not real, believing things that are not true, being suspicious, or having new manic symptoms may occur. Call the doctor right away if there are any new or worsening mental symptoms during treatment.
- if you or your child have 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 the doctor right away if any signs of unexplained wounds appear on fingers or toes while taking Vyvanse.
- if your child is having slowing of growth (height and weight); Vyvanse may cause this serious side effect. 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.
- if you or your child are pregnant, breast-feeding, or plan to become pregnant or breastfeed.

#### What are possible side effects of Vyvanse?

The most common side effects of Vyvanse reported in ADHD studies include:

anxiety

decreased appetite

diarrhea

dizziness

dry mouth

irritability

loss of appetite

nausea

trouble sleeping

upper stomach pain

vomiting

weight loss

The most common side effects of Vyvanse reported in studies of adults with moderate to severe B.E.D. include:

dry mouth

constipation

trouble sleeping

feeling jittery

trouble sleeping • feeling j
decreased appetite • anxiety

increased heart rate

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

Vyvanse<sup>®</sup> (lisdexamfetamine dimesylate) is a registered trademark of Shire LLC. Vyvanse is available in 10, 20, 30, 40, 50, 60 and 70 mg capsules.

*DSM-5*<sup>®</sup> is a registered trademark of the American Psychiatric Association.

#### For further information please contact:

#### **Investor Relations**

Sarah Elton-Farr <u>seltonfarr@shire.com</u> +44 1256 894157

Media

Scott Santiamo@npsp.com +1 908 432 6962

#### **About Shire**

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 are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas, such as Opthalmics.

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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;
- 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 Shire's products may affect 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 manufacture of Shire's products is subject to extensive oversight by various regulatory agencies. Regulatory approvals or interventions associated with 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;
- Shire has a portfolio of products in various stages of research and development. The successful development of these products 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 Shire's ability to sell or market products profitably. Fluctuations in buying or distribution patterns by such customers can adversely affect 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 and organizations. Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect 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 NPS Pharmaceuticals Inc. 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 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, 2014.