Press Release

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Shire Submits NDA to FDA for New Formulation of Vyvanse® (lisdexamfetamine dimesylate) CII as Chewable Tablets

New formulation, in adherence with approved indications, intended for children, adolescents and adults with difficulty swallowing or opening capsules

Lexington, Mass. – April 14, 2016 – For U.S. Audiences Only – Shire plc (LSE: SHP, NASDAQ: SHPG) recently submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for a new, alternate formulation of Vyvanse® (lisdexamfetamine dimesylate) as a chewable tablet for patients who may have difficulty swallowing or opening a capsule. Vyvanse capsules can be swallowed whole or consumed by opening and mixing the entire contents into water, orange juice or yogurt. Vyvanse chewable tablets will offer an additional administration option for patients.

In the U.S., Vyvanse capsules are indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients ages six 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. The proposed indications for Vyvanse chewable tablets are the same as the currently FDA-approved indications for Vyvanse capsules.

“Patients are always our top priority at Shire. We’re looking forward to FDA review of this application because Vyvanse chewable tablets provide an additional option for patients who may prefer taking medication in this manner,” said Perry Sternberg, Head of Neuroscience, Ophthalmics and Commercial Excellence, Shire.

Two clinical pharmacology studies (SHP489-126 and SHP489-127) formed the basis of this application. Study SHP489-126 demonstrated that the chewable tablet formulation is bioequivalent to the capsule formulation after a single oral dose administration of each. Study SHP489-127 established that the chewable tablet formulation is bioequivalent in both a fasting and non-fasting state. Based on these clinical pharmacology studies, the clinical profile of Vyvanse chewable tablets is thought to be comparable to the current formulation.

The Vyvanse chewable tablet has not been approved in any country. The tablet would be administered orally, once daily in the morning. Patients must follow the full instructions outlined in the Medication Guide for taking Vyvanse.

About Vyvanse

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. 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 is pregnant, breast-feeding, or plan to become pregnant or breast-feed.

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
- increased heart rate
- anxiety
- trouble sleeping
- constipation
- decreased appetite
- feeling jittery

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

Vyvanse capsules are available in 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg strengths.

About ADHD

Attention-Deficit/Hyperactivity Disorder (ADHD) 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.

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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 B.E.D.

Binge Eating Disorder (B.E.D.), recognized as a distinct disorder in 2013 by the American Psychiatric Association (APA), 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 over eating during a binge eating episode and marked distress over their binge 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. Adults with moderate to severe B.E.D. usually binge four to thirteen times per week. Only a doctor or other trained health care professional (HCP) can diagnose B.E.D. and determine an appropriate treatment plan.

B.E.D. is the most common eating disorder in U.S. adults and is more prevalent than anorexia and bulimia combined. The disorder 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.

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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 Rare Diseases, Neuroscience, Gastrointestinal and Internal Medicine and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas, such as Ophthalmics.

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Forward-Looking Statements

Statements included herein that are not historical facts, including without limitation statements concerning our announced business combination with Baxalta and the timing and financial and strategic benefits thereof, our 20x20 ambition that targets $20 billion in combined product sales by 2020, as well as other targets for future financial results, capital structure, performance and sustainability of the combined company, the combined company's future strategy, plans, objectives, expectations and intentions, the anticipated timing of clinical trials and approvals for, and the commercial potential of, inline or pipeline products 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, the following:

- the proposed combination with Baxalta may not be completed due to a failure to satisfy certain closing conditions, including any shareholder or regulatory approvals or the receipt of applicable tax opinions;
- disruption from the proposed transaction with Baxalta may make it more difficult to conduct business as usual or maintain relationships with patients, physicians, employees or suppliers;
- the combined company may not achieve some or all of the anticipated benefits of Baxalta's spin-off from Baxter International, Inc. ("Baxter") and the proposed transaction may have an adverse impact on Baxalta's existing arrangements with Baxter, including those related to transition, manufacturing and supply services and tax matters;
- the failure to achieve the strategic objectives with respect to the proposed combination with Baxalta may adversely affect the combined company's financial condition and results of operations;
- products and product candidates may not achieve 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 the combined company's products may affect future revenues, financial condition and results of operations, particularly if there is pressure on pricing of products to treat rare diseases;
- supply chain or manufacturing disruptions may result in declines in revenue for affected products and commercial traction from competitors; regulatory actions associated with product approvals or 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;
- the successful development of products in various stages of research and development 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 the combined company's ability to sell or market products profitably, and fluctuations in buying or distribution patterns by such customers can adversely affect the combined company's revenues, financial condition or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to the combined company'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 the combined company's ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on the combined company's revenues, financial condition or results of operations;
- Shire is undergoing a corporate reorganization and was the subject of an unsuccessful acquisition proposal and the consequent uncertainty could adversely affect the combined company's ability to attract and/or retain the highly skilled personnel needed to meet its strategic objectives;

- failure to achieve the strategic objectives with respect to Shire's acquisition of NPS Pharmaceuticals Inc. or Dyax Corp. ("Dyax") may adversely affect the combined company's financial condition and results of operations;
- the combined company will be dependent on information technology and its systems and infrastructure face certain risks, including from service disruptions, the loss of sensitive or confidential information, cyber-attacks and other security breaches or data leakages that could have a material adverse effect on the combined company's revenues, financial condition or results of operations;
- the combined company may be unable to retain and hire key personnel and/or maintain its relationships with customers, suppliers and other business partners;
- difficulties in integrating Dyax or Baxalta 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, Dyax's or Baxalta's filings with the Securities and Exchange Commission ("SEC"), including those risks outlined in "ITEM 1A: Risk Factors" in Shire's and Baxalta's Annual Reports on Form 10-K for the year ended December 31, 2015.

All forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Except to the extent otherwise required by applicable law, we do not undertake any obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.