

Lisdexamfetamine Dimesylate Approved to Treat Attention Deficit Hyperactivity Disorder in Adults

BASINGSTOKE, England and PHILADELPHIA, April 23/PRNewswire-FirstCall/ -- Shire plc (LSE: SHP) (NASDAQ: SHPGY), the global specialty biopharmaceutical company, today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for VYVANSE(TM) (lisdexamfetamine dimesylate), for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults. VYVANSE, introduced in July 2007 for the treatment of ADHD in children aged 6 to 12 years, is now the first and only once-daily prodrug stimulant approved to treat adults with ADHD. In its first eight months of availability, more than one million VYVANSE prescriptions have been filled.

"We are very pleased with this FDA approval of the adult indication for VYVANSE," said Matthew Emmens, Chief Executive Officer of Shire. "This approval provides physicians a new treatment option that can help their adult patients by significantly improving their ADHD symptoms. VYVANSE has been well accepted by the medical community. With Shire's experience as a leader in the development and commercialization of ADHD medications, we are confident that this approval for adult patients will help continue to increase prescription share and volume of VYVANSE."

"Many people may think of ADHD as only a childhood disorder but the fact is that the majority of children diagnosed with ADHD still have symptoms as an adult. These symptoms can significantly impact them at work, home and in relationships, where they have important responsibilities," said David W. Goodman, assistant professor of psychiatry and behavioral sciences at Johns Hopkins University School of Medicine and director of the Adult Attention Deficit Disorder Center of Maryland. "The good news is that in a clinical study with adults, one daily dose of VYVANSE significantly improved ADHD symptoms of inattention, such as the ability to focus and organize, as well as hyperactivity and impulsivity."

Since VYVANSE became available for children with ADHD in July 2007, the product has achieved a U.S. market share of 6.9 percent based on weekly branded prescription volume VYVANSE formulary coverage has been positive, with the top six managed care plans now covering the product in a preferred formulary position.

VYVANSE is a therapeutically inactive prodrug, in which d-amphetamine is covalently bonded to l-lysine, and after oral ingestion it is converted to pharmacologically active d-amphetamine. The conversion of VYVANSE to d-amphetamine is not affected by gastrointestinal pH and is unlikely to be affected by alterations in normal GI transit times.

VYVANSE is currently available in three dosage strengths of 30 mg, 50 mg and 70 mg, each for once-daily dosing. Additional dosage strengths of 20 mg, 40 mg and 60 mg VYVANSE have also been FDA-approved and are expected to be available in pharmacies this summer.

Additional information about VYVANSE and Full Prescribing Information are available at <http://www.vyvanse.com>.

VYVANSE Significantly Improved ADHD Symptoms

The phase III pivotal trial that led to the FDA approval of VYVANSE to treat adults with ADHD was a double-blind, placebo-controlled, four-week study with dose escalations in 414 adults aged 18 to 55 years. In this study, adults with ADHD experienced significant improvements in ADHD symptom control within one week of treatment with once-daily VYVANSE.

Treatment with VYVANSE at all doses studied (30 mg, 50 mg, 70 mg) was significantly more effective than placebo, providing a reduction in ADHD Rating Scale (ADHD-RS-IV) scores ranging from 16.2 to 18.6 points at endpoint. The ADHD-RS-IV is a standardized test for assessing symptoms of ADHD and for assessing their response to treatment. This scale, which contains 18 items, is based on the ADHD diagnostic criteria as defined in the APA's Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision(R), a publication of the American Psychiatric Association.

Investigators also measured the efficacy of VYVANSE with the Clinical Global Impressions-Improvement (CGI-I) scale and found that the percentage of subjects taking VYVANSE that rated improved ranged from 57 to 61 percent across all doses and was significantly greater than placebo.(1) The CGI-I scale is a standard assessment used to rate the severity of a patient's illness and improvement over time.

The most commonly reported adverse events in this study were decreased appetite, difficulty falling asleep, and dry mouth.

About ADHD

ADHD is one of the most common psychiatric disorders in children and adolescents. Approximately 7.8 percent of all school-aged children, or about 4.4 million U.S. children aged 4 to 17 years, have been diagnosed with ADHD at some point in their lives, according to the U.S. Centers for Disease Control and Prevention (CDC). The disorder is also estimated to affect 4.4 percent of U.S. adults aged 18-44 based on results from the National Comorbidity Survey Replication, a nationally representative household survey, which used a lay-administered diagnostic interview to assess a wide range of DSM-IV disorders. ADHD is a neurobiological disorder that manifests as a persistent pattern of inattention and/or hyperactivity-impulsivity that is more frequent and severe than is typically observed in individuals at a comparable level of development. To be properly diagnosed with ADHD, a child needs to demonstrate at least six of nine symptoms of inattention; and/or at least six of nine symptoms of hyperactivity/impulsivity; the onset of which appears before age 7 years; that some impairment from the symptoms is present in two or more settings (e.g., at school and home); that the symptoms continue for at least six months; and that there is clinically significant impairment in social, academic or occupational functioning and the symptoms cannot be better explained by another psychiatric disorder.

Although there is no "cure" for ADHD, there are accepted treatments that specifically target its symptoms. The most common standard treatments include educational approaches, psychological or behavioral modification, and medication.

Source: Shire