Long-Term 12-Month Safety Data Presented on ADHD Patch DAYTRANA (Methylphenidate Transdermal System)

Study Shows ADHD Patch Provides Tolerable and Effective Symptom Control.

Boston (PRWEB) October 29, 2007 -- Shire plc (LSE: SHP, NASDAQ: SHPGY, TSX: SHQ), the global specialty biopharmaceutical company, announced that data from a 12-month study of DAYTRANATM (methylphenidate transdermal system), the Attention Deficit Hyperactivity Disorder (ADHD) patch, demonstrated that DAYTRANA provided significant ADHD tolerability and symptom control improvement in children aged 6 to 12 years. The study data was presented today at a major scientific and educational meeting of child and adolescent psychiatrists held in Boston, and is consistent with data previously presented.

“In our study, children with ADHD experienced effective ADHD symptom control improvement when using DAYTRANA for 12 months, improving their ability to maintain focus and concentration in and outside of the classroom,” reported investigator Frank A. López, M.D., neurodevelopmental pediatrician at the Children’s Developmental Center, Winter Park, Fla. “Importantly, this year-long study showed that DAYTRANA maintained a favorable safety profile throughout the study period, with adverse events consistent with previous DAYTRANA studies.”

Shire’s DAYTRANA is the first and only patch medication approved by the U.S. Food and Drug Administration (FDA) to treat the symptoms of ADHD in children aged 6 to 12 years. The study results demonstrate that adverse events associated with DAYTRANA were similar to other methylphenidate products. The most common adverse events reported in this study were decreased appetite, headache, upper respiratory tract infection, cough, fever, and decreased weight. When worn for the recommended nine hours, efficacy has been demonstrated from the first time point measured (two hours) through the 12-hour time point. Because DAYTRANA is a patch, physicians may recommend that patients shorten the wear time if shorter duration of effect is desired or to help manage the potential for late-day side effects, such as lack of appetite or difficulty sleeping.

López added, “DAYTRANA’s novel patch delivery system offers physicians and parents of children with ADHD a convenient, non-oral option to individualize ADHD treatment to meet their children’s changing schedules.”

While this study evaluated the safety and effectiveness of DAYTRANA for up to 12 months, DAYTRANA has not been studied versus placebo for longer than 7 weeks. Physicians, who prescribe DAYTRANA for long-term use, should periodically re-evaluate patients to assess the usefulness of DAYTRANA for the individual patient.

The study was supported by funding from Shire.

About ADHD:
Approximately 7.8 percent of all school-age 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). ADHD is one of the most common psychiatric disorders in children and adolescents. ADHD is a neurobiological psychiatric 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.

For further information please contact:

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Long-Term (Up To 12 Months) Use of the Methylphenidate Transdermal System  
Frank A. López, M.D., Oscar G. Bukstein, M.D., Robert L. Findling, M.D., John M. Turnbow, M.D., Jonathan Rubin, M.D.  
Children’s Developmental Center, Winter Park, FL; Western Psychiatric Institute and Clinic, Pittsburgh, PA; University Hospitals Case Medical Center, Cleveland, OH; Westex Clinical Investigations, Lubbock, TX; Shire Development Inc., Wayne, PA.

Important Safety Information

Tell your doctor about any heart conditions, including structural abnormalities, your child or a family member may have. Inform your doctor immediately if the child develops symptoms that suggest heart problems, such as chest pain or fainting.

Daytrana should not be used if the child has: significant anxiety, tension, or agitation; allergies to methylphenidate or other ingredients of Daytrana; glaucoma; discontinued in the last 14 days or is taking a monoamine oxidase inhibitor (MAOI); tics, or family history or diagnosis of Tourette’s syndrome.

Tell your doctor before using Daytrana if the child: is being treated for or has symptoms of depression (e.g. sadness, worthlessness, or hopelessness) or bipolar disorder; has family history of tics; has abnormal thoughts or visions, hears abnormal sounds, or has been diagnosed with psychosis; has had seizures or abnormal EEGs; has or has had high blood pressure; exhibits aggressive behavior or hostility. Tell your doctor immediately if the child develops any of these conditions/symptoms while using Daytrana.
In clinical studies, side effects were generally mild to moderate. The most common side effects reported with Daytrana were decreased appetite, sleeplessness, sadness/crying, twitching, weight loss, nausea, vomiting, tics, and affect lability (mood swings). Aggression, new abnormal thoughts/behaviors, mania, and growth suppression have been associated with use of drugs of this type. Tell your doctor if the child has blurred vision while using Daytrana.

Abuse of Daytrana can lead to dependence.

Daytrana should be applied daily to clean, dry skin, which is free of any cuts or irritation. Skin redness or itching is common with Daytrana. Allergic skin rash may occur.

For Full Prescribing Information go to www.DAYTRANA.com

Notes to editors:
SHIRE PLC
Shire’s strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on attention deficit and hyperactivity disorder (ADHD), human genetic therapies (HGT), gastrointestinal (GI) and renal diseases. The structure is sufficiently flexible to allow Shire to target new therapeutic areas to the extent opportunities arise through acquisitions. Shire’s in-licensing, merger and acquisition efforts are focused on products in niche markets with strong intellectual property protection either in the US or Europe. Shire believes that a carefully selected portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results.

For further information on Shire, please visit the Company’s Web site: www.shire.com.

"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 affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of pharmaceutical research, product development (including the successful development of JUVISTA® (Human TGFb3)), manufacturing and commercialization (including the launch and establishment in the market of VYVANSE); the impact of competitive products, including, but not limited to the impact of those on Shire’s Attention Deficit and Hyperactivity Disorder (“ADHD”) franchise; patents, including but not limited to, legal challenges relating to Shire’s ADHD franchise; government regulation and approval, including but not limited to the expected product approval date of INTUNIV™ (guanfacine) extended release (ADHD) and GA-GCB (Gene-Activated Glucocerebrosidase); Shire’s ability to secure new products for commercialization and/or development; Shire’s ability to benefit from its acquisition of New River Pharmaceuticals Inc.; and other risks and uncertainties detailed from time to time in Shire plc’s filings with the Securities and Exchange Commission, particularly Shire plc’s Annual Report on Form 10-K for the year ended December 31, 2006.

Daytrana™ is a trademark of Shire Pharmaceuticals Ireland Limited.

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Online Web 2.0 Version
You can read the online version of this press release here.