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Non-safety-related voluntary recall of a limited portion of Daytrana[®] (methylphenidate transdermal system) patches announced

PHILADELPHIA – December 3, 2009 – Shire plc (LSE: SHP, NASDAQ: SHPGY), the global specialty biopharmaceutical company, today announced a voluntary recall of five lots and voluntary market withdrawal of one lot of the Attention-Deficit/Hyperactivity Disorder (ADHD) patch Daytrana[®]. Shire is taking this action because some Daytrana patches do not meet or in the future may not meet their release liner removal specification, and as a result, patients and caregivers could have difficulty removing the liners.

This action is not due to safety issues. All Daytrana patches can continue to be used unless the release liner cannot be removed or the patches are damaged while being opened. The current supply levels of Daytrana should be sufficient to ensure that patients can continue to have their Daytrana prescriptions filled at their local pharmacy.

Physicians, patients, and caregivers who have questions about Daytrana should call Shire's Daytrana customer service line at **1-800-828-2088, option 1**, and pharmacists should call **1-888-871-7113**.

Noven Pharmaceuticals, Inc. continues to manufacture and Shire continues to promote DAYTRANA in the United States. DAYTRANA is licensed globally to Shire by Noven. Shire and Noven have notified the United States Food and Drug Administration (FDA) of this voluntary action.

Shire and Noven are committed to continuing ongoing quality assurance monitoring and data analysis of DAYTRANA and may implement additional voluntary actions. Shire and Noven continue to actively pursue enhancements to DAYTRANA and are working with the FDA to implement changes intended to enhance the usability of DAYTRANA.

Daytrana lots affected by this action are:

Voluntary Recall

| Strength | Count | NDC# | Lot Number(s) | Expiry |
|-----------------|--------------|--------------|------------------------|---------------|
| 20 mg | 30 | 54092-554-30 | 33988, 34174, 34175 | 12/31/2010 |
| 30 mg | 30 | 54092-555-30 | 33990, 34179 | 12/31/2010 |

Voluntary Market Withdrawal

| Strength | Count | NDC# | Lot Number(s) | Expiry |
|-----------------|--------------|--------------|----------------------|---------------|
| 30 mg | 30 | 54092-555-30 | 33991 | 12/31/2010 |

Important Safety Information

Daytrana is indicated for the treatment of ADHD in children aged 6 to 12 years.

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. Talk to your health care provider if your child experiences slowing of growth (height and weight). Children should have their height and weight checked periodically while taking Daytrana. Your healthcare provider may stop Daytrana treatment if a problem is found during these check-ups. 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.

About ADHD

ADHD is one of the most common psychiatric disorders in children and adolescents.¹ Worldwide prevalence of ADHD is estimated at 5.3 percent (with large variability), according to a comprehensive systematic review of this topic published in 2007 in the *American Journal of Psychiatry*.² In the United States, approximately 7.8 percent of all school-aged children, or about 4.4 million children aged 4 to 17 years, have been diagnosed with ADHD at some point in their lives, according to the Centers for Disease Control and Prevention (CDC).³

ADHD is a psychiatric behavioral 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.^{4,5} The specific etiology of ADHD is unknown and there is no single diagnostic test for this disorder.¹ Adequate diagnosis requires the use of medical and special psychological, educational, and social resources, utilizing diagnostic criteria such as *Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV®)* or *International Classification of Diseases 10 (ICD-10)*.^{1,4,5}

Although there is no cure for ADHD, there are accepted treatments that specifically target its symptoms. Standard treatments include educational approaches, psychological or behavioral modification, and medication.¹

For further information please contact:

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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 hyperactivity disorder (ADHD), human genetic therapies (HGT) and gastrointestinal (GI) diseases as well as opportunities in other therapeutic areas to the extent they arise through acquisitions. Shire's in-licensing, merger and acquisition efforts are focused on products in specialist markets with strong intellectual property protection and global rights. Shire believes that a carefully selected and balanced 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: <http://www.shire.com>.

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, the Company's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, risks associated with: the inherent uncertainty of research, development, approval, reimbursement, manufacturing and commercialization of the Company's Specialty Pharmaceutical and Human Genetic Therapies products, as well as the ability to secure and integrate new products for commercialization and/or development; government regulation of the Company's products; the Company's ability to manufacture its products in sufficient quantities to meet demand; the impact of competitive therapies on the Company's products; the Company's ability to register, maintain and enforce patents and other intellectual property rights relating to its products; the Company's ability to obtain and maintain government and other third-party reimbursement for its products; and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission.

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References

1. Pliszka S and the AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2007; 46(7):894-921.
2. Polanczyk G, de Lima MS, Horta BL, et al. The worldwide prevalence of ADHD: a systematic review and metaregression analysis. *Am J Psych*. 2007; 164:942-948.
3. Mental health in the United States: Prevalence of diagnosis and medication treatment for attention-deficit/hyperactivity disorder, United States, 2003. *MMWR*. 2005;54(34):842-847.
4. *Diagnostic and Statistical Manual of Mental Disorders*. 4th ed., Text Revision (*DSM-IV-TR*[®]). Arlington, VA: American Psychiatric Publishing; 2000:85-93.
5. *International Classification of Diseases, 10th ed.*, (ICD-10). World Health Organization; 2007: Chapter 5,F90. <http://www.who.int/classifications/apps/icd/icd10online/>. Accessed October 12, 2009.