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PRESS RELEASE

NOVEN COMPLETES ACQUISITION OF DAYTRANA[®] METHYLPHENIDATE TRANSDERMAL SYSTEM (CII) FROM SHIRE

First and Only Patch for ADHD Now to be Marketed and Sold by Noven Therapeutics

Miami, FL, October 1, 2010 -- Noven Pharmaceuticals, Inc. today announced that it has completed the acquisition of global rights to Daytrana[®] (methylphenidate transdermal system) from Shire plc ("Shire").

Daytrana was originally licensed globally to Shire by Noven in 2003 and was approved and launched in the U.S. in 2006. The product is indicated for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD") in patients 6 to 17 years old. Daytrana should be used as part of a total treatment program for ADHD that may include counseling or other therapies. Shire's net sales of the product for the first half of 2010 were \$34.7 million.

Daytrana will be marketed and sold by Noven Therapeutics, Noven's specialty pharmaceuticals marketing and sales unit. Noven Therapeutics currently promotes the oral prescription products Pexeva[®], Stavzor[®] and Lithobid[®] to psychiatrists and other appropriate physicians in the U.S. Daytrana product availability will not be interrupted or otherwise affected by the acquisition or by the transfer of the product to Noven.

Jeffrey Eisenberg, Noven's President and Chief Executive Officer, said: "We are very pleased to complete the acquisition and to add Daytrana – a product developed and manufactured by Noven – to the portfolio of products that we market and sell through Noven Therapeutics. I extend my thanks and appreciation to Shire for their partnership and support during the period of their license of Daytrana, and to both the Noven and Shire teams who made the transaction happen. Daytrana continues to represent an important therapeutic option in the treatment of ADHD. As an organization, we're excited to begin active promotion of the product, with the goal of increasing awareness of Daytrana and helping patients, physicians and caregivers manage the symptoms of ADHD."

For further information, please contact:

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About Daytrana

The Daytrana patch is a prescription central nervous system (brain) stimulant medicine used to treat ADHD in children 6 to 17 years old. Daytrana may help increase attention and decrease impulsive and hyperactive behavior. The Daytrana patch should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Important Safety Information

IMPORTANT:

Daytrana is a controlled substance (CII) because it can be abused or lead to dependence. Keep Daytrana in a safe place to protect it from theft. Selling or giving away Daytrana may harm others and is against the law.

Tell the prescribing doctor if your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.

The Daytrana patch should not be used if your child is very anxious, tense, or agitated; has an eye problem called glaucoma; has tics (repeated movements or sounds that cannot be controlled) has a diagnosis or family history of seizures or has a diagnosis or family history of Tourette's syndrome; or have had an abnormal brain wave test (EEG); is taking a monoamine oxidase inhibitor (MAOI) medicine or has discontinued an MAOI medicine in the last 2 weeks; is pregnant or breastfeeding; is allergic to methylphenidate or any other ingredients of Daytrana.

Serious heart problems have been reported with the Daytrana patch or other stimulant medicines including:

- sudden death in people with heart problems or heart defects
- stroke and heart attack in adults
- increased blood pressure and heart rate

Tell the doctor if your child or a family member has any heart problems, heart defects, or increased blood pressure and heart rate. Remove the Daytrana patch and call the doctor right away if your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while using Daytrana.

Serious mental (psychiatric) problems have been reported with the Daytrana patch or other stimulant medicines including:

- new or worse aggressive behavior, hostility, anger or irritability
- new or worse bipolar illness or mania (an extreme increase in activity or talking)
- new or worse psychosis (hearing or seeing things that are not real, being suspicious, or distrustful, believing things that are not true)
- other unusual or extreme changes in behavior or mood

Tell the doctor about any mental problems your child or family members have including suicide or depression, bipolar illness, mania, or psychosis. Call the doctor right away if your child has any new or worsening mental symptoms or problems while using the Daytrana patch.

Serious side effects such as seizures (this usually happens in children with a history of seizures), slowing of growth (weight and height), eyesight changes or blurred vision have been reported with the Daytrana patch. Allergic skin rash may occur. **Stop using Daytrana and see the doctor right away if swelling, bumps, or blisters happen at or around where the patch is applied.**

If the patch is worn longer than 9 hours in a day, or if more than 1 patch is worn at a time, too much medicine has been applied. Avoid exposing the Daytrana patch to direct external heat sources such as hair dryers, heating pads, electric blankets, heated water beds, or other heat sources while wearing the patch. Heating the patch could cause too much medicine to pass into your child's body and cause serious side effects.

Your child should have his or her height and weight checked often while using the Daytrana patch and your doctor may stop treatment if a problem is found during these check-ups.

Most common side effects seen while using the Daytrana patch include skin problems (redness, small bumps, itching) where the patch is applied, poor appetite, nausea, vomiting, stomach pain, weight loss, tics, trouble sleeping, mood swings, and dizziness.

Please see Full Prescribing Information and Medication Guide for Daytrana, including the warning regarding abuse and dependence.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

About Noven

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's business and operations are focused in three principal areas – transdermal drug delivery and related manufacturing, the Novogyne joint venture, and Noven Therapeutics, Noven's specialty pharmaceutical unit. Noven is committed to developing and offering products and technologies that meaningfully benefit patients, its customers and its industry partners. Previously a publicly-traded company, Noven was acquired in August 2009 by Hisamitsu Pharmaceutical Co., Inc., headquartered in Tosu, Saga and Tokyo. Noven is now a stand-alone operating subsidiary of Hisamitsu, and is positioned to serve as Hisamitsu's U.S. growth platform in prescription pharmaceuticals. For more information about Noven, visit www.noven.com. For information about Hisamitsu, visit www.hisamitsu.co.jp/english.

【参考資料】

この資料は、Noven Pharmaceuticals, Inc. (以下、Noven 社) が 2010 年 10 月 1 日 (米国東部時間) に発表したプレスリリースを日本語に翻訳したもので、内容および解釈については英語が優先されます。

「Important Safety Information about Daytrana®」については、本取引とは直接関係ありませんので割愛しています。

Noven 社が Shire 社から メチルフェニデート経皮吸収システム製剤 Daytrana®の取得を完了

最初で唯一の ADHD 治療用パッチ製剤を Noven Therapeutics が販売することになりました

2010 年 10 月 1 日、フロリダ州マイアミ - Noven Pharmaceuticals 社は本日、Shire 社の関連会社 (以下「Shire 社」) 所有であった Daytrana® (メチルフェニデート経皮吸収システム製剤) に関する全ての権利の取得が完了したと発表しました。

Daytrana®は当初、2003 年に Shire 社へ全世界を対象にライセンス提供され、2006 年に米国で承認、販売開始されました。当製品は注意欠陥・多動性障害 (「ADHD」) の 6 歳から 17 歳の患者の治療に、またカウンセリングあるいは他の治療を含む ADHD のトータル治療プログラムの一部として適応されます。Shire 社の 2010 年上半期の当製品売上高は 3,470 万ドルでした。

Daytrana®のマーケティングと販売は、Noven 社のスペシャリティファーマ事業部門の Noven Therapeutics が担当します。現在、Noven Therapeutics は経口処方薬の Pexeva®、Stavzor®、Lithobid®を米国内の精神科および他科の医師に対して販売促進しています。Daytrana の持つ可能性は、今回の権利の移転によってなんら阻害されることはありません。

Noven 社の社長兼 CEO である Jeffrey Eisenberg 氏は「Noven が開発し製造する Daytrana®を Noven Therapeutics の製品ラインナップに加えられるのは非常に喜ばしいことです。この Daytrana®のライセンス期間に受けた Shire 社のご協力と今回の権利移転に尽力した両社のスタッフに感謝の意を表します。Daytrana®は ADHD の治療における重要な選択肢であり続けます。当社組織として Daytrana®の認知度を上げて、患者、医療従事者、介護者が ADHD と上手につきあうことができるように支援することを最終目標に、本商品のプロモーションを始めることに対して興奮を覚えています。」と述べています。

Noven 社について

Noven Pharmaceuticals 社は、医療用医薬品の研究、開発、製造、企画、販売に携わるスペシャリティファーマです。

Noven 社は次の 3 つの事業分野に経営資源を集中しています。

- TDDS（経皮吸収治療システム）および関連製品の製造
- 合併事業である Novogyne 社
- スペシャリティファーマ事業

Noven 社は患者や顧客、業界のパートナーに重要な利益をもたらす製品および技術を開発、提供するため尽力しています。以前、株式公開会社だった Noven 社は、2009 年 8 月、佐賀県鳥栖市と東京都に本社のある久光製薬株式会社を買収されました。Noven 社は現在、久光製薬の独立運営子会社であり、医療用医薬品事業において久光製薬グループが米国で成長する基盤としての役割を担っています。Noven 社についての詳細情報は、www.noven.com、久光製薬についての詳細情報は、www.hisamitsu.co.jp/english をご覧ください。

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