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PRESS RELEASE

NOVEN TO ACQUIRE DAYTRANA[®] METHYLPHENIDATE TRANSDERMAL SYSTEM FROM SHIRE

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

Miami, FL, August 10, 2010 -- Noven Pharmaceuticals, Inc. today announced that it has entered into a Product and Trademark Acquisition Agreement (the "Agreement") with affiliates of Shire plc ("Shire") pursuant to which Noven will acquire global rights to Daytrana[®] (methylphenidate transdermal system) from Shire.

Daytrana[®], developed and manufactured by Noven, was originally licensed globally to Shire 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 a part of a total treatment program for ADHD that may include counseling or other therapies. Shire's net sales of the product in 2009 were \$71 million.

The Agreement provides that Noven will acquire substantially all rights and assets related to Daytrana[®], including the product's New Drug Application, and will assume certain related liabilities. Shire will continue to commercialize the product through closing of the transaction, scheduled for October 1, 2010. Additional transaction terms are confidential.

Once transferred to Noven, Daytrana[®] will be marketed and sold by Noven Therapeutics, Noven's specialty pharmaceuticals marketing and sales unit, with U.S. promotion of the product expected to begin in March 2011. Noven Therapeutics currently promotes the oral prescription products Pexeva[®], Stavzor[®] and Lithobid[®] to psychiatrists and other target physicians in the U.S.

Jeffrey Eisenberg, Noven's President and Chief Executive Officer, said: "We are excited to add Daytrana[®] to the product portfolio of Noven Therapeutics. Since 2006, Daytrana[®] has been an important therapeutic alternative for patients with ADHD and their physicians. Applying the focused strategies and resources of Noven Therapeutics, we believe Noven will be well-positioned to continue to raise awareness of Daytrana[®], with the ultimate goal of helping patients manage their ADHD."

For further information, please contact:

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Important Safety Information about Daytrana[®]

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 and prevent misuse or abuse. 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.

Daytrana 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), a diagnosis or family history of seizures, a diagnosis or family history of Tourette's syndrome; or 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; or is allergic to methylphenidate or any other ingredients of Daytrana.

Serious heart problems have been reported with Daytrana 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 Daytrana 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 Daytrana.

Serious side effects such as seizures (this usually happens in people with a history of seizures), slowing of growth (weight and height), eyesight changes or blurred vision have been reported with Daytrana. 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 Daytrana has been used. Your child should not use hair dryers, heating pads, electric

blankets, heated water beds or other heat sources while wearing a Daytrana patch. This 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 taking Daytrana and your doctor may stop treatment if a problem is found during these check-ups.

Most common side effects seen with Daytrana 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 including 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 8 月 10 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® を獲得

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 8 月 10 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」) と、製品および商標の買収契約 (以下「契約」) を締結し、Shire 社所有の Daytrana® (メチルフェニデート経皮吸収システム製剤) の全ての権利を Noven 社が取得することになると発表しました。

Noven 社によって開発、製造された 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 2009 年の当製品売上高は 7,100 万ドルでした。

契約により、Noven 社はの新薬申請 (NDA) 承認権を含む Daytrana® に関する実質上全ての権利および資産を取得し、かつ関連する責任の一部を引き受けることとなります。Shire 社は、2010 年 10 月 1 日に予定されている本契約の発効日までは当製品の営業活動を継続します。その他の取引条件等については非公開とされています。

Noven 社へ譲渡された後、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、2011 年 3 月には米国で当製品の販促活動が開始される予定です。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。

Noven 社の社長兼 CEO である Jeffrey Eisenberg 氏は「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。2006 年以降、ADHD の患者と医師にとって、Daytrana® は治療における重要な選択肢となっています。Noven Therapeutics の経営資源を適用することによって、患者が 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、Noven 社は Daytrana® の認知度を上げ続けるための体制を整えていくことができると信じています。」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
- － 合弁事業である 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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