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## P R E S S   R E L E A S E

### XELSTRYM™ (DEXTROAMPHETAMINE) TRANSDERMAL SYSTEM, CII, TO BE REVEALED AS AVAILABLE SOON AT THE 2023 AMERICAN PROFESSIONAL SOCIETY OF ADHD AND RELATED DISORDERS (APSARD) CONFERENCE

– XELSTRYM, the first and only amphetamine patch will be available by prescription in Q1 2023 –

**January 10, 2023 – Miami, FL and Jersey City, NJ** – Noven Pharmaceuticals, Inc., (Noven), a wholly owned subsidiary of Hisamitsu Pharmaceutical Co., Inc. focusing on the development of transdermal treatments, announced today that XELSTRYM™ (dextroamphetamine) transdermal system, CII, the first and only [FDA-approved](#) amphetamine patch for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in adults and pediatric patients six years and older, will be available across the U.S. for healthcare professionals to prescribe later in the first quarter of 2023.<sup>1</sup> In anticipation of this, Noven will be publicly presenting XELSTRYM in a branded capacity for the first time at the American Professional Society of ADHD and Related Disorders (APSARD) Conference being held January 13-15 in Orlando, Florida.

As a Platinum Sponsor of the APSARD Conference, Noven is hosting an industry symposium focusing on ADHD in adults, which will be presented by Greg Mattingly, MD, Associate Clinical Professor, Washington University and President Elect of APSARD. "Noven's involvement to highlight ADHD in adults at this year's conference strikes a particular chord of excitement as we've learned efforts are underway to develop and publish guidelines in 2023 for the diagnosis and treatment of ADHD in adults, which will address this critical need for healthcare providers and patients," said Naruhito Higo, PhD, Chief Executive Officer of Noven Pharmaceuticals. "And as the availability of XELSTRYM draws near, Noven continues to pursue our mission of advancing ADHD patient care with diligence and passion, and we look forward to continuing collaboration with key stakeholders in ADHD at APSARD and beyond."

In addition to the symposium and the presentation of two posters by the Medical Affairs Team, Noven is honored to sponsor the 2023 APSARD Early Career/Trainee Award, which will be presented during the conference.

XELSTRYM was [approved by FDA](#) in March 2022.

#### About Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is one of the most common neurodevelopmental disorders of childhood. It is usually first diagnosed in childhood and often lasts into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviors (may act without thinking about what the result will be), or be overly active. ADHD can last into adulthood. Some adults have ADHD but have never been diagnosed. The symptoms can cause difficulty at work, at home, or with relationships. Symptoms can become more severe when the demands of adulthood increase and may look different at older ages, for example, hyperactivity may appear as extreme restlessness.

#### About XELSTRYM™

XELSTRYM is the first and only FDA-approved, once-daily amphetamine transdermal patch for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years

and older. XELTRYM should be applied 2 hours before an effect is needed and removed within 9 hours after application.

## **IMPORTANT SAFETY INFORMATION**

### **What is XELTRYM?**

XELTRYM is a central nervous system stimulant prescription medicine used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in adults and children 6 years and older. It is not known if XELTRYM is safe and effective in children younger than 6 years of age.

## **IMPORTANT SAFETY INFORMATION**

**Abuse and dependence: XELTRYM, other amphetamine-containing medicines, and methylphenidate have a high chance for abuse and can cause physical and psychological dependence. Your healthcare provider (HCP) should check you or your child for signs of abuse and dependence before and during treatment with XELTRYM.**

- Tell your HCP if you or your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.
- Your HCP can tell you how physical and psychological dependence and drug addiction are different.

**XELTRYM is a federally controlled substance (CII) because it contains amphetamine that can be a target for people who abuse prescription medicines or street drugs.** Keep XELTRYM in a safe place to protect it from theft. Never sell or give your XELTRYM to anyone else because it may cause death or harm to them and it is against the law.

### **Do not use XELTRYM if you or your child are:**

- Allergic to amphetamine or any of the ingredients in XELTRYM. See the end of the Medication Guide for a complete list of ingredients in XELTRYM.
- Taking or have taken within the past 14 days a medicine called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or the intravenous medicine called methylene blue.

### **XELTRYM can cause serious side effects, including:**

- **Heart-related problems, including:**
  - sudden death, stroke, and heart attack in adults
  - sudden death in children who have heart problems or heart defects
  - increased blood pressure and heart rate

Your HCP should check you or your child carefully for heart problems before starting treatment with XELTRYM. Tell your HCP if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems. Your HCP should check your or your child's blood pressure and heart rate regularly during treatment with XELTRYM. **Call your HCP or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with XELTRYM.**

- **Mental (psychiatric) problems, including:** new or worse behavior and thought problems, new or worse bipolar illness, new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms. Tell your HCP about any mental problems you or your child have or about a family history of suicide, bipolar illness, or depression. **Call your HCP right away if you or your child have any new or worsening mental symptoms or problems**

**during treatment with XELTRYM, especially hearing, seeing or believing things that are not real, or new manic symptoms.**

- **Slowing of growth (height or weight) in children.** Children should have their height and weight checked often while on XELTRYM. Your HCP may stop treatment with XELTRYM if your child is not growing or gaining height or weight as expected.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon):** fingers or toes may feel numb, cool, painful, fingers or toes may change color from pale, to blue, to red. Tell your HCP if you or your child has any numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.  
**Call your HCP right away if you or your child have any signs of unexplained wounds appearing on fingers or toes while using XELTRYM.**
- **Serotonin syndrome:** symptoms such as agitation, fast heartbeat, flushing, seizures, coma, sweating, loss of coordination, confusion, dizziness, tremors, stiff muscles, muscle twitching, seeing or hearing things that are not real (hallucinations), changes in blood pressure, high body temperature (hyperthermia), nausea, vomiting, or diarrhea may occur.  
Stop using XELTRYM and call your HCP or go to the emergency room if symptoms occur.  
Serotonin syndrome may occur if XELTRYM is taken with certain medicines and may be life-threatening.
- **Allergic skin rash (contact sensitization):** Stop using XELTRYM and tell your HCP right away if you or your child develop swelling or blisters at or around the application site.
- **Application site reactions** have happened while wearing XELTRYM and after removal of the patch. Symptoms include pain, itching, burning feeling, redness, discomfort, or swelling at the application site. Call your HCP if you or child develop any application site reactions that do not resolve on their own.

#### **Before taking XELTRYM tell your healthcare provider if you:**

- Are pregnant or plan to become pregnant. It is not known if XELTRYM may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. XELTRYM can pass into your milk. Do not breastfeed while taking XELTRYM. Talk to your doctor about the best way to feed your baby if you take XELTRYM.

#### **What should I avoid while using XELTRYM?**

- Do not drive, operate heavy machinery, or do other potentially dangerous activities until you know how XELTRYM affects you.
- Avoid exposing the application site to direct external heat sources such as hair dryers, heating pads, electric blankets, heat lamps, saunas, hot tubs, and heated water beds as exposure to heat can cause too much medicine to pass into your body and cause serious side effects.

#### **What are the possible side effects of XELTRYM?**

- The most common side effects of XELTRYM include:
  - decreased appetite
  - headache
  - trouble sleeping
  - stomach pain
  - nausea
  - increased blood pressure
  - muscle twitching (tics)
  - vomiting
  - irritability
  - increased heart rate

**Please read the [Medication Guide](#) and [Full Prescribing Information](#) including the Boxed Warning.**

To report suspected Adverse Reactions, contact Noven at 1-800-455-8070 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

There is a pregnancy registry for women who are exposed to XELTRYM during pregnancy. The purpose of the registry is to collect information about the health of women exposed to XELTRYM and their baby. If you or your child becomes pregnant during treatment with XELTRYM, talk to your HCP about registering with the National Pregnancy Registry for Psychiatric Medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/>

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**About Noven Pharmaceuticals, Inc.**

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's mission is to develop and offer pharmaceutical products that meaningfully benefit patients around the world, with a commitment to advancing patient care through transdermal drug delivery. Noven is a standalone operating subsidiary of Japan-based Hisamitsu Pharmaceutical Co., Inc., serving as Hisamitsu's U.S. platform for prescription pharmaceuticals, and helping Hisamitsu bring the benefits of patch therapy to the world. For more information about Noven, visit <http://www.noven.com>. For information about Hisamitsu, visit <https://global.hisamitsu>.

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