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PRESS RELEASE

FDA Approves Once-Daily XELSTRYM™ (dextroamphetamine) Transdermal System, CII, for the Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in Adults and Pediatric Patients 6 Years and Older

- *The First-and-Only Approved Amphetamine Patch for the Treatment of ADHD*

Miami, FL and Jersey City, NJ – March 23, 2022 -- Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., today announced that the U.S. Food and Drug Administration (FDA) has approved XELSTRYM™ (dextroamphetamine) transdermal system, CII, for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) for adults and pediatric patients 6 years and older.[1] XELSTRYM is the first-and-only FDA-approved transdermal amphetamine patch.

The efficacy and safety of XELSTRYM for the treatment of ADHD in pediatric patients 6 to 17 years was evaluated in a multi-center, randomized, double-blind, placebo-controlled, cross-over design, modified analog classroom study. The primary efficacy endpoint was observed as measured by the Swanson, Kotkin, Agler, M-Flynn, and Pelham Scale (SKAMP) total score demonstrating a significant separation from placebo with the use of XELSTRYM. The most common adverse reactions (incidence ≥2% and greater than the rate for placebo) in pediatric patients 6 to 17 years treated with XELSTRYM were decreased appetite, headache, insomnia, tic, abdominal pain, vomiting, nausea, irritability, blood pressure increased, and heart rate increased. The efficacy and safety of XELSTRYM in adults was based on the comparable XELSTRYM pharmacokinetic profile in adults and children, and the established bridge to adequate and well-controlled studies of lisdexamfetamine.

“The availability of XELSTRYM underscores the need for a non-oral amphetamine treatment for ADHD,” said Greg Mattingly, MD, Associate Clinical Professor of Psychiatry at The Washington University School of Medicine in St. Louis, Missouri. “As a once-daily transdermal patch, XELSTRYM provides clinicians and their patients, many with varying daily schedules, the ability to share in the decision making process of determining when to apply and subsequently, when to remove the patch to optimize the desired benefit of individualized treatment.”

XELSTRYM should be applied 2 hours before an effect is needed and removed within 9 hours after application. Dose titration and final dosage should be individualized depending on clinical response and tolerability. XELSTRYM will be available in dosage strengths of 4.5 mg/9 hours, 9 mg/9 hours, 13.5 mg/9 hours and 18 mg/9 hours.[1]

“FDA’s approval of XELSTRYM provides people living with ADHD a new option to manage a medication schedule that fits their individual lifestyle,” said Joel Lippman, M.D., Chief Operating Officer and Chief Medical Officer, Noven Pharmaceuticals, Inc. “As the first amphetamine transdermal patch available for the treatment of ADHD in adults and pediatrics, this is a significant milestone for Noven and our goal of offering new options for clinicians, caregivers and patients for the treatment of ADHD. This approval enables our team to finalize preparations for commercial launch in the U.S. as early as the second half of this year.”

Please read the Medication Guide and Full Prescribing Information including the Boxed Warning.

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

IMPORTANT SAFETY INFORMATION

What is XELSTRYM?
XELSTRYM 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 XELSTRYM is safe and effective in children younger than 6 years of age.

IMPORTANT SAFETY INFORMATION

Abuse and dependence: XELSTRYM, 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 XELSTRYM.

- 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.

XELSTRYM 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 XELSTRYM in a safe place to protect it from theft. Never sell or give your XELSTRYM to anyone else because it may cause death or harm to them and it is against the law.

Do not use XELSTRYM if you or your child are:

- Allergic to amphetamine or any of the ingredients in XELSTRYM. See the end of the Medication Guide for a complete list of ingredients in XELSTRYM.
- 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.

XELSTRYM 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 XELSTRYM. 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 XELSTRYM. **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 XELSTRYM.

- **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 XELSTRYM, 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 XELSTRYM. Your HCP may stop treatment with XELSTRYM 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 XELSTRYM.
- **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 XELSTRYM and call your HCP or go to the emergency room if symptoms occur. Serotonin syndrome may occur if XELSTRYM is taken with certain medicines and may be life-threatening.
- **Allergic skin rash (contact sensitization):** Stop using XELSTRYM 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 XELSTRYM 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 XELSTRYM tell your healthcare provider if you:

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

What should I avoid while using XELSTRYM?

- Do not drive, operate heavy machinery, or do other potentially dangerous activities until you know how XELSTRYM 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 XELSTRYM?

- The most common side effects of XELSTRYM 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.

There is a pregnancy registry for females who are exposed to XELSTRYM during pregnancy. The purpose of the registry is to collect information about the health of females exposed to XELSTRYM and their baby. If you or your child becomes pregnant during treatment with XELSTRYM, 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/

XEL-5003-16 (2.0)

3/2022

About ADHD
Attention-Deficit/Hyperactivity Disorder (ADHD) is one of the most common neurodevelopmental disorders characterized by inattention, hyperactivity and impulsivity that can interfere with functioning or development. It is usually first diagnosed in childhood and often lasts 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 change overtime as a person ages.[2]

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 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 stand-alone 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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[1] XELSTRYM™ (dextroamphetamine) transdermal system, CII [package insert]. Miami, FL. Noven Pharmaceuticals, Inc. [March, 2022].
[2] National Institute of Mental Health. ADHD. [Internet]. Available from: https://www.nimh.nih.gov/health/topics/attention-deficit-hyperactivity-disorder-adhd. Accessed March 2022.