Neos Therapeutics Launches Adzenys ER™ (amphetamine) Extended-Release Oral Suspension in U.S. for the Treatment of ADHD in Patients 6 Years and Older

February 26, 2018

Marks third Neos ADHD product launch in less than 2 years

DALLAS and FORT WORTH, Texas, Feb. 26, 2018 (GLOBE NEWSWIRE) --

Neos Therapeutics, Inc. (Nasdaq:NEOS), a pharmaceutical company focused on developing, manufacturing and commercializing innovative extended-release (XR) products using its proprietary modified-release drug delivery technologies, today announced the U.S. launch of Adzenys ER™ (amphetamine) Extended-Release Oral Suspension, making it Neos’ third ADHD product launch in less than two years. The two other products in the Neos ADHD Product Portfolio are Adzenys XR-ODT® (amphetamine) Extended-Release Orally Disintegrating Tablets and Cotempla XR-ODT™ (methylphenidate) Extended-Release Orally Disintegrating Tablets.

“The launch of Adzenys ER oral suspension is yet another example of our commitment to helping meet the different needs of patients with ADHD, their caregivers and healthcare professionals,” said Vipin K. Garg, Ph.D., President and CEO of Neos Therapeutics. “Our growing ADHD Product Portfolio represents the strength of our unique technology platform and our ability to develop, manufacture and commercialize products.”

Adzenys ER oral suspension was approved by the U.S. Food and Drug Administration (FDA) on September 15, 2017. It is a once-daily, extended-release liquid medication that does not require refrigeration or reconstitution at the pharmacy level. Adzenys ER oral suspension utilizes the same proprietary modified-release drug delivery technology as Adzenys XR-ODT and is bioequivalent to Adderall XR.

Adzenys ER, Adzenys XR-ODT, and Cotempla XR-ODT are federally controlled substances (CII). Central nervous system (CNS) stimulants (amphetamine and methylphenidate-containing products) have a high potential for abuse and dependence. Physicians should assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence.

“The launch of Adzenys ER oral suspension provides physicians like me with another tool and, more importantly, another opportunity to further meet the individual needs of patients with ADHD,” said Rakesh Jain, MD, Clinical Professor, Department of Psychiatry, Texas Tech University Health Sciences Center School of Medicine at Permian Basin, Midland, Texas. “This once-daily liquid formulation has the potential to play a key role in helping patients manage their ADHD symptoms. Liquid formulations may allow the prescriber to adjust or fine-tune the dose that is right for their patients.”

IMPORTANT SAFETY INFORMATION for Adzenys XR-ODT and Adzenys ER

Adzenys XR-ODT and Adzenys ER are federally controlled substances (CII) because they can be abused or lead to dependence. Keep both Adzenys XR-ODT and Adzenys ER in a safe place to prevent misuse and abuse. Selling or giving away Adzenys XR-ODT or Adzenys ER may harm others and is against the law. Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Who should not take Adzenys XR-ODT or Adzenys ER?
Do not take Adzenys XR-ODT or Adzenys ER if you or your child is:

- allergic to amphetamine or any ingredients in Adzenys XR-ODT or Adzenys ER.
- taking or has taken an anti-depression medicine called monoamine oxidase inhibitor (MAOI) within the past 14 days.
- you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems. This is important because sudden death has occurred in people with heart problems or defects, and sudden death, stroke and heart attack have happened in adults. Your doctor should check for heart problems prior to prescribing either Adzenys XR-ODT or Adzenys ER and will check you or your child’s blood pressure and heart rate during treatment.
- you or your child has mental problems, or a family history of suicide, bipolar illness, or depression. This is important because the following could occur: new or worse behavior and thought problems, new or worse bipolar illness, new psychotic symptoms (hearing voices, believing things that are not true, are suspicious) or new manic symptoms.
- you or your child has circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon). Fingers or toes may feel numb, cool, painful, sensitive to temperature and/or change color from pale, to blue, to red.
- you or your child has any signs of unexplained wounds appear on fingers or toes while taking either Adzenys XR-ODT or Adzenys ER.
• you or your child is having symptoms of serotonin syndrome which may happen when Adzenys XR-ODT or Adzenys ER is taken with certain other medicines and may be life threatening. Call your doctor or go to the nearest hospital emergency room if you have any of the following symptoms: agitation, hallucinations, coma or other changes in mental status, problems controlling your movements or muscle twitching, fast heartbeat, high or low blood pressure, sweating or fever, muscle stiffness or tightness, nausea, vomiting or diarrhea.

• your child is having slowing of growth (height and weight). Your child should have his or her height and weight checked often while taking either Adzenys XR-ODT or Adzenys ER. The doctor may stop treatment if a problem is found during these check-ups.

• you or your child has kidney problems. Your doctor may lower the dose.

• you or your child is, or plans to become pregnant. If you or your child becomes pregnant during treatment with either Adzenys XR-ODT or Adzenys ER, talk to your doctor about registering with the National Pregnancy Registry for Psychostimulants.

• you or your child is breastfeeding, or plans to breastfeed. You or your child should not breastfeed while taking either Adzenys XR-ODT or Adzenys ER.

• you or your child takes any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Adzenys XR-ODT and Adzenys ER and some medicines may interact with each other and cause serious side effects.

Do not start any new medicine while taking either Adzenys XR-ODT or Adzenys ER without talking to your doctor first.

**What should I avoid while taking Adzenys XR-ODT or Adzenys ER?**

• You should avoid drinking alcohol.

**Common side effects for Adzenys XR-ODT and Adzenys ER include:**

1. **Children 6 – 12 Years:** Decreased appetite, problems sleeping, stomach pain, extreme mood change, vomiting, nervousness, nausea, and fever.
2. **Children 13 – 17 Years:** Decreased appetite, problems sleeping, stomach pain and weight loss, and nervousness.
3. **Adults:** Dry mouth, decreased appetite, problems sleeping, headache, weight loss, nausea, anxiety, restlessness, dizziness, fast heartbeat, diarrhea, weakness, and urinary tract infections.

These are not all the possible side effects of Adzenys XR-ODT and Adzenys ER. Call your doctor for medical advice about side effects.

**What are Adzenys XR-ODT and Adzenys ER?**

Adzenys XR-ODT and Adzenys ER are central nervous system (CNS) stimulant prescription medicines used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. Adzenys XR-ODT and Adzenys ER are federally controlled substances (CII) because they contain amphetamine that can be a target for people who abuse prescription medicines or street drugs. Keep both Adzenys XR-ODT or Adzenys ER in a safe place to protect it from theft. Selling or giving away your Adzenys XR-ODT or Adzenys ER may cause death or harm to others and is against the law.

For additional safety information for Adzenys XR-ODT, click here for the [Medication Guide](#) and [Prescribing Information](#) and discuss with your doctor.

For additional safety information for Adzenys ER, click here for the [Medication Guide](#) and [Prescribing Information](#) and discuss with your doctor.

**IMPORTANT SAFETY INFORMATION for Cotempla XR-ODT**

Cotempla XR-ODT is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep in a safe place to protect it from theft. Selling or giving away your Cotempla XR-ODT may cause death or harm to others and is against the law.

**Who should not take Cotempla XR-ODT?**

Do not give Cotempla XR-ODT to your child if they are:

• allergic to methylphenidate or any ingredients in Cotempla XR-ODT.
• taking or has taken an anti-depression medicine called monoamine oxidase inhibitor (MAOI) within the past 14 days.

**What is the most important information I should know about Cotempla XR-ODT?**

Cotempla XR-ODT can cause serious side effects. Tell your healthcare provider about health conditions, including if your child:

• has ever abused or been dependent on alcohol, prescription medicines, or street drugs. Cotempla XR-ODT has a high chance for abuse and can cause physical and psychological dependence.
• has any heart problems, heart defects, high blood pressure, or a family history of these problems. This is important because sudden death has occurred in people with heart problems or defects. Increased blood pressure and heart rate have been reported. Your healthcare provider should check for heart problems prior to prescribing Cotempla XR-ODT and will check your child’s blood pressure and heart rate regularly during treatment. Call the healthcare provider or go to the nearest hospital emergency room right away if your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment.
• has mental problems, or a family history of suicide, bipolar illness, or depression. This is important because the following could occur: new or worse behavior and thought problems, new or worse bipolar illness, new psychotic symptoms (hearing voices, or seeing or believing things that are not real) or new manic symptoms. **Call your healthcare provider right away if there are any new or worsening mental symptoms or problems during treatment.**

• develops painful and prolonged erections (priapism). Priapism has happened in males who take products that contain methylphenidate. **Get medical help right away if your child develops priapism.**

• has circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon). Fingers or toes may feel numb, cool, painful, and/or change color from pale, to blue, to red. Tell your healthcare provider if your child has numbness, pain, skin color change, or sensitivity to temperature in their fingers or toes. **Call the healthcare provider right away if any signs of unexplained wounds appear on fingers or toes while taking Cotempla XR-ODT.**

• is having slowing of growth (height and weight). Your child should have his or her height and weight checked often while taking Cotempla XR-ODT. Treatment may be stopped if your child is not gaining weight or height.

• is pregnant or plans to become pregnant. It is not known if Cotempla XR-ODT will harm the unborn baby. If your child becomes pregnant during treatment with Cotempla XR-ODT, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants.

• is breastfeeding, or plans to breastfeed. You and your healthcare provider should decide if your child will take Cotempla XR-ODT or breastfeed.

• takes any medicines, including prescription and over-the-counter medicines (especially for depression, including MAOIs), vitamins, and herbal supplements. Cotempla XR-ODT and some medicines may interact with each other and cause serious side effects, or sometimes the dose of the other medicine will need to be adjusted.

**Do not start any new medicine while taking Cotempla XR-ODT without talking to your healthcare provider first.**

**What should I avoid during treatment with Cotempla XR-ODT?**

• You should avoid drinking alcohol during treatment with Cotempla XR-ODT.

**Common side effects of Cotempla XR-ODT include:**

Decreased appetite, trouble sleeping, nausea, vomiting, indigestion, stomach pain, weight loss, anxiety, dizziness, irritability, mood swings, increased heart rate, and increased blood pressure.

These are not all the possible side effects of Cotempla XR-ODT. Call your healthcare provider for medical advice about side effects.

**What is Cotempla XR-ODT?**

Cotempla XR-ODT is a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 to 17 years of age. Cotempla XR-ODT is a federally controlled substance (CII) because it contains methylphenidate that can be a target for people who abuse prescription medicines or street drugs. Keep Cotempla XR-ODT in a safe place to protect it from theft. Selling or giving away your Cotempla XR-ODT may cause death or harm to others and is against the law.

For additional safety information, click here for **Full Prescribing Information** and **Medication Guide** and discuss with your healthcare provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**About ADHD**

According to the Centers for Disease Control and Prevention, ADHD is one of the most common neurodevelopment disorders of childhood and can continue through adolescence and adulthood. In fact, ADHD is estimated to affect 5 percent of children and 2.5 percent of adults in the U.S. ii

Symptoms include inattentiveness, hyperactivity and impulsiveness. These patterns of behavior are seen in many settings (school, home, work) and can impact performance and relationships.

Stimulant medications such as amphetamine and methylphenidate are first-line pharmacological therapies for treating ADHD, and extended-release formulations of these medications allow for once-daily dosing. Most of the existing treatment options are tablets or capsules, which need to be swallowed intact or in some cases sprinkled on certain foods or fluids and ingested immediately.

**About Neos Therapeutics**

Neos Therapeutics, Inc. (NASDAQ:NEOS) is a pharmaceutical company focused on developing, manufacturing and commercializing products utilizing its proprietary modified-release drug delivery technology platforms. Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see [Full Prescribing Information](#), including Boxed WARNING), Cotempla XR-ODT™ (methylphenidate) extended-release orally disintegrating tablets (see [Full Prescribing Information](#), including Boxed WARNING), and Adzenys-ER™ (amphetamine) extended-release oral suspension (see [Full Prescribing Information](#), including Boxed WARNING), all for the treatment of ADHD, are the first three approved products using the Company’s extended-release technology platform. Additional information about Neos is available at [www.neostx.com](http://www.neostx.com).

**Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Neos Therapeutics, Inc., including statements concerning the commercialization of our ADHD product portfolio, our marketing plans, the therapeutic potential of our products and other statements containing the words “will,” “would,” “continue,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, without limitation, our ability to market and sell our products and other factors discussed in the “Risk Factors” section of Neos’ Annual Report on Form 10-K for the year ended December 31, 2016, which is on file with the SEC, as updated by any subsequently filed SEC filings, including Neos’ Quarterly Reports on Form 10-Q. Any forward-looking statements contained in this press release speak only as of the date hereof, and Neos expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.
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