

Aytu BioPharma, Inc Continues Availability of Adzenys XR-ODT® as the Only FDA-Approved Orally Disintegrating Tablet (ODT) Medication that is Bioequivalent to Adderall XR® for ADHD Patients

Aytu RxConnect Providing Access Relief to Patients Amid Ongoing Generic Adderall® Supply Disruption

ENGLEWOOD, CO / January 10, 2023 / Millions of ADHD patients in the United States rely on FDA approved treatments to control their ADHD symptoms and many of them are currently struggling to fill their prescription due to a prolonged supply disruption for generic Adderall XR (mixed salts of a single-entity amphetamine product) extended-release capsules, CII. Many of these patients may not be aware that there's an FDA-approved, bioequivalent treatment option which is widely available. As the only FDA-approved Orally Disintegrating Tablet bioequivalent to Adderall XR, Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets, CII is bridging the access gap resulting from the current supply disruption, as well as the shortage of Adderall IR.

Manufactured and marketed by Aytu BioPharma, Inc. (the Company or "Aytu") (NASDAQ:AYTU), a commercial stage pharmaceutical and consumer health company providing pediatric-focused prescription drugs and cost-effective consumer health solutions, Adzenys XR-ODT is available as a potential treatment option to Adderall XR in six equivalent strengths.

"What I'm finding in my practice is that many people taking Adderall XR and its generics to manage their ADHD are concerned and confused as to their options when it is not available," says Joe Gagnon, Psychiatric-Mental Health Nurse Practitioner. "People with ADHD already battle mental health issues, so reassurance they are receiving equivalent treatment is imperative. Adzenys XR-ODT has proven not only to be a sufficient replacement for my patients, many intend to continue to take it even after the shortage ends," adds Gagnon. "I would encourage anyone who may find themselves adversely affected by the Adderall supply shortage to speak with their healthcare provider to find out if they can make the switch to Adzenys XR-ODT as an alternative to Adderall XR."

As healthcare insurance resets in January, many ADHD patients with high deductibles may face another challenge in accessing their medication. However, patients facing insurance challenges can gain access to Adzenys XR-ODT via Aytu's proprietary RxConnect program and the company's network of more than 1,000 retail pharmacies. The program is designed specifically to help patients navigate complex treatment journeys. It enables affordable, predictable patient access to Aytu Rx products and reduces out-of-pocket costs by 50 percent. In most cases, commercially insured patients will pay no more than \$35 for their monthly prescription of Adzenys XR-ODT.

About Adzenys XR-ODT

Adzenys XR-ODT is available by prescription only, is bioequivalent to Adderall XR, and is the only FDA-approved, extended-release, orally disintegrating tablet formulation of amphetamine. Adzenys XR-ODT is indicated for the treatment of ADHD in patients six years and older. Adzenys XR-ODT is available at retail pharmacies and through the Aytu RxConnect patient support program.

Visit www.AdzenysXRODT.com for more information including dose selection and titration schedule.

To locate an Adzenys XR-ODT pharmacy in a patient's area please visit www.AytuRxConnect.com.

What is Adzenys XR-ODT?

Adzenys XR-ODT is a central nervous system stimulant prescription medicine used for the treatment of ADHD in patients 6 years and older.

Important Safety Information



CONTRAINDICATIONS

- Known hypersensitivity to amphetamine or other ingredients in Adzenys XR-ODT. Angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products.
- Taking a monoamine oxidase inhibitor (MAOI), or have taken an MAOI within the past 14 days. Hypertensive crisis can occur.

Important Safety Information

Adzenys XR-ODT is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Adzenys XR-ODT in a safe place to prevent misuse and abuse. Selling or giving away Adzenys XR-ODT 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?

Do not take Adzenys XR-ODT if you or your child is:

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

Adzenys XR-ODT is a stimulant medicine. Tell your doctor about health conditions, including if:

- 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 Adzenys XR-ODT and will check you or your child's blood pressure and heart rate during treatment. Call the doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking Adzenys XR-ODT.
- 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. Call the doctor right away if there are any new or worsening mental symptoms during treatment.
- 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. Call the doctor right away if any signs of unexplained wounds appear on fingers or toes while taking Adzenys XR-ODT.
- your child is having slowing of growth (height and weight). Your child should have his or her height and weight checked often while taking Adzenys XR-ODT. 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.
- you or your child is breastfeeding or plans to breastfeed. You should not breastfeed while taking Adzenys XR-ODT.
- you or your child takes any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Adzenys XR-ODT and some medicines may interact with each other and cause serious side effects.
- Do not start any new medicine while taking Adzenys XR-ODT without talking to your doctor first.

What should I avoid while taking Adzenys XR-ODT?

- drinking alcohol

Common side effects of Adzenys XR-ODT include:

- Decreased appetite and problems sleeping.

- Children 6 – 12 Years also include: Stomach pain, extreme mood change, vomiting, nervousness, nausea, and fever.
- Children 13 – 17 Years also include: Stomach pain and weight loss.
- Adults also include: Dry mouth, headache, weight loss, nausea, anxiety, restlessness, dizziness, fast heart beat, diarrhea, weakness, and urinary tract infections.

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

For additional safety information, click here for Prescribing Information and Medication Guide and discuss with your doctor.

To report suspected adverse reactions, contact Aytu BioPharma at 855-AYTU-BIO (855-298-8246). 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 ADHD

According to the Centers for Disease Control and Prevention, ADHD is one of the most common childhood disorders 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. 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 the standard of care for treating ADHD, and extended-release (XR) formulations of these medications allow for once-daily dosing. Most of the existing treatment formulations are tablets or capsules, which need to be swallowed intact or in some cases sprinkled on certain foods or fluids and ingested immediately. Orally disintegrating tablets differ from traditional tablets and capsules in that they are designed to disintegrate in the mouth, rather than being swallowed whole.

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company commercializing a portfolio of commercial prescription therapeutics and consumer health products. The Company's prescription products include Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) and Cotelma XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) for the treatment of attention deficit hyperactivity disorder (ADHD), as well as Karbinal® ER (carbinoxamine maleate), an extended-release antihistamine suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines

available in various formulations for infants and children with fluoride deficiency. Aytu's consumer health segment markets a range of over-the-counter medicines, personal care products, and dietary supplements addressing a range of common conditions including diabetes, allergy, hair regrowth, and gastrointestinal conditions. To learn more, please visit aytubio.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this press release, are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as 'may,' 'will,' 'should,' 'forecast,' 'could,' 'expect,' 'suggest,' 'believe,' 'estimate,' 'continue,' 'anticipate,' 'intend,' 'plan,' or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. All statements other than statements of historical facts contained in this press release, are forward-looking statements. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others, the willingness of doctors to prescribe Adzenys. We also refer you to (i) the risks described in 'Risk Factors' in Aytu's Annual Report on Form 10-K, in Quarterly Reports filed on Form 10-Q, and in the other reports and documents it files with the Securities and Exchange Commission.

Contacts for Investors:

Mark Oki, Chief Financial Officer
Aytu BioPharma, Inc.
moki@aytubio.com

Robert Blum or Roger Weiss
Lytham Partners
AYTU@lythampartners.com

Media Contact:

David Griffith
Interdependence Public Relations
davidg@interdependence.com

ADDERALL XR® is a registered trademark of Takeda Pharmaceuticals U.S.A., Inc.

ADDERALL® is a registered trademark of Takeda Pharmaceuticals U.S.A., Inc. under license to Duramed Pharmaceuticals, Inc.

SOURCE: Aytu BioPharma, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/734512/Aytu-BioPharma-Inc-Continues-Availability-of-Adzenys-X-R-ODTR-as-the-Only-FDA-Approved-Orally-Disintegrating-Tablet-ODT-Medication-that-is-Bioequivalent-to-Adderall-XRR-for-ADHD-Patients>