Aytu BioPharma Announces FDA Orange Book Listing of Newly Issued Patent for Cotempla XR-ODT®

ENGLEWOOD, CO / March 23, 2022 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, today announced that its newly issued US patent No. 11,166,947 for Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablet is now listed in the U.S. Food and Drug Administration (FDA) publication, "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the "Orange Book." The Cotempla XR-ODT patent covers methods of use for the effective pediatric dosing of methylphenidate for the treatment of attention deficit hyperactivity disorder (ADHD).

Cotempla XR-ODT is an orally disintegrating tablet containing methylphenidate and is indicated for the treatment of ADHD in patients 6 to 17 years old. FDA approved the New Drug Application for Cotempla XR-ODT in June 2017. The United States Patent and Trademark Office (USPTO)-issued US patent No. 11,166,947 entitled "Effective Dosing of a Child for the Treatment of ADHD with Methylphenidate" is now listed in the FDA's Orange Book and carries a patent term to at least 2038. The listing of this patent extends the Orange Book patent exclusivity for Cotempla XR-ODT by over five years.

"We are pleased to expand and strengthen our intellectual property protection for Cotempla through the listing of this latest patent in the FDA's Orange Book," commented Josh Disbrow, chief executive officer of Aytu BioPharma. "Our prescription ADHD portfolio continues to grow given the growing need for ADHD medications and the unique clinical profile of both Cotempla XR-ODT and Adzenys XR-ODT as the only orally disintegrating tablets approved to treat ADHD. We are excited to protect this key commercial product through this new patent issuance and look forward to continuing to make Cotempla XR-ODT available for patients who need this important medication."

Patents listed in the Orange Book cover drugs that the FDA has approved and deemed both safe and effective for the general public's use. Inclusion in the book's list of patents can make it easier for drug makers to monitor for new generic drugs that could potentially arrive on the U.S. market and infringe on their patents.

About Cotempla XR-ODT

Cotempla XR-ODT is a central nervous system stimulant available in an extended-release orally disintegrating tablet formulation containing methylphenidate. Cotempla XR-ODT is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 to 17 years of age. To view the full prescribing information as well as the BLACK BOX WARNING visit cotemplaxrodt.com.

IMPORTANT SAFETY INFORMATION FOR PATIENTS

Cotempla XR-ODT is a federally controlled substance (CII) because it can be abused or lead to dependence. 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.

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.

About Aytu BioPharma, Inc.
Aytu BioPharma is a pharmaceutical company with a portfolio of commercial prescription therapeutics and consumer health products, and a growing therapeutics pipeline focused on treating rare, pediatric-onset disorders. The company’s prescription products include Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) and Cotempla 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 carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency. Aytu is also building a therapeutic pipeline, which includes AR101 (enzastaurin), a PKCβ inhibitor in development for the treatment of vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disease typically diagnosed in childhood resulting in high morbidity and a significantly shortened lifespan, and for which there are no currently approved treatments. AR101 has received Orphan Drug designation from the U.S. Food and Drug Administration and the European Medicines Agency. 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. Forward-looking statements, including but not limited to any statements regarding the intellectual property and product information presented in this press release. 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 ability to protect our intellectual property, the future growth potential of our commercial portfolio, the anticipated start dates, durations and completion dates and the potential safety and efficacy of our product candidates. We also refer you to the risks described in ‘Risk Factors’ in Aytu’s Annual and Quarterly Reports on Form 10-K and 10-Q and in the other reports and documents it files with the Securities and Exchange Commission.

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View source version on accesswire.com:
https://www.accesswire.com/694281/Aytu-BioPharma-Announces-FDA-Orange-Book-Listing-of-Newly-Issued-Patent-for-Cotempla-XR-ODTR