Aytu BioScience Announces Tuzistra XR Co-Promotion Agreement with Poly Pharmaceuticals

Co-promotion nearly doubles Tuzistra XR sales force

Poly's geographic footprint covers approximately 750,000 antitussive prescriptions annually accounting for approximately $128 million in annual revenue

ENGLEWOOD, CO / September 4, 2019 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, announced today a co-promotion agreement for Tuzistra® XR with Poly Pharmaceuticals ("Poly"). This commercial collaboration will nearly double the Tuzistra XR sales force to approximately 60 representatives across the United States. Poly is a privately-held specialty pharmaceutical company focused primarily on cough, allergy, and other respiratory conditions and has actively promoted prescription antitussives since its founding in 1980.

The co-promotion agreement term is three years, with the ability to extend beyond the initial term upon the companies' mutual agreement. Poly will receive commission payments based on Tuzistra XR prescriptions generated from physician targets within Poly's geographic footprint. Poly's geographic footprint covers approximately 750,000 antitussive prescriptions annually accounting for approximately $128 million in annual revenue.

Poly's sales force started physician and pharmacy promotion of Tuzistra XR on September 3rd and expects to promote to approximately 5,000 prescribers through the 2019-2020 cough and allergy season.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, "This is an exciting development for Aytu as we partner with Poly to nearly double our promotional efforts for Tuzistra XR. Poly's experience in the antitussive category goes back decades, and we're looking forward to having their experienced sales team promote the unique patient benefits of Tuzistra XR, the only 12-hour codeine-based antitussive syrup, to their established base of clinician prescribers."

Chase Williams, President of Poly Pharmaceuticals, commented, "We're pleased to be working with the Aytu team on this Tuzistra XR co-promotion and look forward to a strong working relationship into the future. Tuzistra XR is a unique, differentiated product in the antitussive category, and our experience in commercializing antitussives over many years gives us confidence that there will be significant physician interest in this unique 12-hour codeine-based product."

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. The company currently markets Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”). Aytu also has exclusive U.S. and Canadian rights to ZolpiMist™, an FDA-approved, commercial-stage prescription sleep aid indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Aytu recently acquired exclusive U.S. commercial rights to Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in an extended-release oral suspension. Additionally, Aytu is developing MiOXSYS®, a novel, rapid semen analysis system with the potential to become a standard of care for the diagnosis and management of male infertility caused by oxidative stress. MiOXSYS is commercialized outside of the U.S. where it is a CE Marked, Health Canada cleared, Australian TGA approved, Mexican COFEPRAS approved product. Aytu is planning U.S.-based clinical trials in pursuit of 510k de novo medical device clearance by the FDA. Aytu’s strategy is to continue building its portfolio of revenue-generating products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information visit aytubio.com.

About Poly Pharmaceuticals, Inc.

Poly Pharmaceuticals is a privately held specialty pharmaceutical company founded in 1980 by a group of pharmacists focused on developing and marketing branded, generic, and OTC pharmaceutical products. Poly markets a broad range of products for conditions such as cough, cold, allergy, sinusitis, pain relief, and urological health. Poly continues to bring new products to market each year through strategic business alliances, acquisitions, product development, and licensing. Poly is dedicated to developing a portfolio of innovative, safe, and cost-effective medications for patients and caregivers.

IMPORTANT INFORMATION ABOUT TUZISTRA XR

INDICATIONS AND USAGE

TUZISTRA XR is a combination of codeine, an opiate agonist antitussive, and chlorpheniramine, a histamine-1 (H1) receptor antagonist indicated for relief of cough and symptoms associated with upper respiratory allergies or a common cold.

Limitation of Use: Not indicated for pediatric patients under 18 years of age.

IMPORTANT SAFETY INFORMATION

WARNING

DEATH RELATED TO ULTRA-RAPID METABOLISM OF CODEINE TO MORPHINE and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Ultra-Rapid Metabolism
Respiratory depression and death have occurred in children who received codeine following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine due to a CYP2D6 polymorphism.

Concomitant Use with Benzodiazepines, CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.

CONTRAINDICATIONS
Postoperative pain management of children undergoing tonsillectomy and/or adenoidectomy. Patients with known hypersensitivity to codeine, chlorpheniramine, or any of the product components of TUZISTRA XR.

WARNINGS AND PRECAUTIONS

Risk of death in individuals who are ultra-rapid metabolizers: Conversion of codeine into its active metabolite, morphine, may occur more rapidly and completely resulting in higher than expected morphine levels and respiratory depression or death. Some individuals CYP2D6 genotype, which prevalence varies widely, and is estimated at 0.5 to 1% in Chinese and Japanese, 0.5 to 1% in Hispanics, 1 to 10% in Caucasians, 3% in African Americans, and 16 to 28% in North Africans, Ethiopians, and Arabs.

Risks from concomitant use with benzodiazepines or other CNS depressants: Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Dose-related respiratory depression: Use with caution, including when used postoperatively, in patients with pulmonary disease or shortness of breath, or whenever ventilator function is depressed. Overdose of codeine in adults has been associated with fatal respiratory depression, and the use of codeine in children, have been associated with fatal respiratory depression. If respiratory depression occurs, discontinue the drug and use naloxone hydrochloride or other supportive measures as necessary.

Drug dependence: Prescribe with caution that is appropriate to the use of other opioids.

Head injury and increased intracranial pressure: Avoid in patients with head injury, intra-cranial lesions, or increased intracranial pressure.

Activities requiring mental alertness: Avoid engaging in hazardous tasks requiring complete mental alertness such as driving or operating heavy machinery. Avoid concurrent use of alcohol or other central nervous system depressants.

Obstructive bowel disease: Chronic use of opioids, including codeine, may result in constipation or chronic obstructive bowel disease, especially in patients with underlying intestinal motility disorders.

Acute abdominal conditions: Use with caution in patients with acute abdominal conditions.

Dosing: Measure dose with an accurate milliliter measuring device; a household teaspoon is not accurate and could lead to over dosage, resulting in serious adverse reactions.

Special risk patients: Caution in elderly patients and those with asthma, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.

ADVERSE REACTIONS

Common adverse reactions of TUZISTRA XR include: nausea and vomiting, constipation, abdominal distension, abdominal pain, blurred vision, diplopia, visual disturbances, confusion, dizziness, depression, drowsiness, sedation, headache, euphoria, facial dyskinesia, feeling faint, light-headedness, general feeling of discomfort or illness, excitability, nervousness, agitation, restlessness, somnolence, insomnia, dyskinesia, irritability, tremor.

To report SUSPECTED ADVERSE REACTIONS, contact Aytu BioScience, Inc. at 1-855-AYTU BIO (1-855-298-8246) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 presentation, 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. 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: risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors, the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future

regulatory submissions and events, our anticipated future cash position and future events under our current and potential future collaboration. We also refer you to the risks described in ‘Risk Factors’ in Part I, Item 1A of the company’s Annual Report on Form 10-K and in the other reports and documents we file with the Securities and Exchange Commission from time to time.

Contact for Investors:
James Carbonara
Hayden IR
(646)-755-7412

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