

Aytu BioScience Announces Launch of Natesto(R) U.S. Co-Promotion with Acerus Pharmaceuticals

Acerus Launches U.S. Specialty Sales Force; Sales Team Expansion Nearly Doubles Current Natesto Sales Force

Expanded Commercial Operations Expected to Accelerate Natesto Growth in the U.S.

ENGLEWOOD, CO / December 2, 2019 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, today announced the launch of the company's co-promotion with Acerus Pharmaceuticals ("Acerus") which is expected to accelerate the growth of in the United States. Through this expanded commercial relationship, Acerus has launched a U.S.-based specialty sales force promoting Natesto to urologists and endocrinologists. Aytu will continue to recognize all Natesto revenue and promote Natesto to all other physician specialties including internal medicine and family practice.

Natesto total prescriptions grew 30% from fiscal 2018 to 2019, and this commercial partnership is expected to accelerate brand growth through joint promotional efforts and a significantly expanded U.S. presence.

The Natesto co-promotion officially closed November 29, 2019 and was effective December 1, 2019. This agreement significantly increases sales force coverage of targeted testosterone prescribers and puts a higher promotional focus on urologists and endocrinologists. Further, this revised partnership enables Aytu to increase its Natesto promotional efforts in primary care and other specialties.

To accelerate the launch of Acerus' U.S. commercial team, Aytu has agreed to transfer five current sales employees to Acerus as of December 2, 2019. These staff will operate as Acerus employees, but they will remain on Aytu's payroll until the earlier of the date on which Acerus is ready to fully assume the personnel or June 30, 2020. Aytu will deduct the costs of these sales personnel from quarterly payments otherwise owed to Acerus under the revised agreement, with a final accounting to be done once per year. Throughout 2020, Acerus will be building out a complete US-based specialty sales force and other commercial functions, significantly increasing the number of employees working directly on Natesto in the United States.

As previously announced on July 30, 2019, the companies signed an agreement to expand their commercial partnership and amend and restate the original 2016 Natesto exclusive U.S. license agreement. Under the revised agreement, Aytu will remain the exclusive U.S. supplier of Natesto and retain all rights to revenues generated.

Aytu and Acerus will continue to operate a joint commercialization committee in support of Natesto and will closely collaborate on U.S. brand strategy and commercial initiatives.

Josh Disbrow, Aytu BioScience Chief Executive Officer, commented, “We are excited to be launching our co-promotion with Acerus as they launch their sales team. With a coordinated promotional approach, this nearly doubling of the Natesto commercial footprint stands to substantially accelerate Natesto prescription growth. Acerus’ increased commitment to Natesto, as evidenced by their significant investment in launching a U.S. commercial team, is an important step in the evolution of the Natesto growth story. This development, coupled with the two recently announced payer formulary wins, should substantially accelerate Natesto’s growth trajectory.”

Mr. Disbrow continued, “We’re excited to be working with Acerus to increase our reach to physicians around the country. Additionally, with the recent expansion of Aytu’s therapeutic portfolio that now includes ZolpiMist™, Tuzistra® XR, and the recently acquired six-product portfolio from Cerecor, this enhanced commercial arrangement enables us to employ a more distinct focus on primary care physicians to grow our entire product portfolio, while Acerus increases the promotional focus on Natesto with urologists and endocrinologists.”

Aytu will continue to serve as the exclusive U.S. supplier to purchasers of Natesto, and Acerus will receive performance-based commissions on prescriptions generated by urologists and endocrinologists above specified revenue levels. Acerus will assume regulatory and clinical responsibilities and associated expenses and will serve a primary role in the development of key opinion leaders in urology and endocrinology. Aytu will focus on commercial channel management, sales to wholesalers and other purchasing customers, and will direct sales efforts in all other physician specialties.

The revised Natesto license agreement extends the original agreement by at least three years to the later of 2027, the launch of an FDA approved, AB-rated generic equivalent to Natesto, or the expiration or invalidation of the last to expire Natesto patent.

The payment structure currently in place will be replaced with a pay-for-performance commission incentive structure intended to drive Natesto prescription growth across all physician specialties. All previously agreed upon milestone payments payable by Aytu have been removed. Additionally, Acerus will now pay all annual FDA fees, future clinical trial costs, and all regulatory and pharmacovigilance and compliance-related expenses.

Aytu will continue to book Natesto revenue and will pay Acerus quarterly commissions based on sales from prescriptions generated by urologists and endocrinologists.

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 a portfolio of prescription products addressing large primary care and pediatric markets. The primary care portfolio includes (i) **Natesto**[®], the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”), (ii) **ZolpiMist**[™], the only FDA-approved oral spray prescription sleep aid, and (iii) **Tuzistra**[®] XR, the only FDA-approved 12-hour codeine-based antitussive syrup. The pediatric portfolio includes (i) **AcipHex**[®] **Sprinkle**[™], a granule formulation of rabeprazole sodium, a commonly prescribed proton pump inhibitor; (ii) **Cefaclor**, a second-generation cephalosporin antibiotic suspension; (iii) **Karbinal**[®] **ER**, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iv) **Poly-Vi-Flor**[®] and **Tri-Vi-Flor**[®], two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various for infants and children with fluoride deficiency. 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.

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 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
james@haydenir.com

SOURCE: Aytu BioScience, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/568584/Aytu-BioScience-Announces-Launch-of-NatestoR-US-Co-Promotion-with-Acerus-Pharmaceuticals>