

# **Aytu BioScience Announces Study Findings Demonstrating Clinical Improvements in Erectile Function and Mood in Hypogonadal Men Treated with Natesto® Nasal Testosterone Gel**

## **Natesto Improves All Five Domains of Erectile Function**

ENGLEWOOD, Colo., Nov. 30, 2016 — Aytu BioScience, Inc. (OTCQX: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products in the field of urology, today announced the summary of findings that demonstrated significant clinical improvements in erectile function and mood in hypogonadal men treated with Natesto® nasal testosterone gel (NTG). Natesto, Aytu's FDA-approved nasal testosterone gel, was launched in late July 2016.

The multi-center Phase 3 study, which was conducted in the U.S., investigated the safety and efficacy of Natesto nasal testosterone gel administered intranasally to 306 men. Male hypogonadism is a clinical syndrome resulting from failure of the testes to produce physiologic levels of testosterone due to disruption of the hypothalamic-pituitary-gonadal axis and is often characterized by mood disturbances, reduced energy levels, and impaired sexual function. This prospective study quantified observed improvement in these key clinical parameters among men taking Natesto.

The study's investigators reported, "NTG achieves large, clinical improvements in erectile function and mood within 30 days of initiating treatment, with the added bonus of improvements in sexual desire. NTG is a safe, effective, and unique form of testosterone therapy and is approved for use in the United States." The results of this study are expected to be presented at an upcoming scientific conference.

"This study further validates the safety and efficacy of Natesto, the only FDA-approved nasally administered testosterone replacement therapy and demonstrates clear improvements in many of the physiologic and psychological effects often experienced by men with hypogonadism," said Josh Disbrow, Chief Executive Officer of Aytu BioScience, Inc. "Specifically, for the first time this study showed that, due to Natesto's unique pharmacokinetic profile, men experiencing mood disturbances, reduced energy levels, and impaired sexual function saw improvements in these parameters in as little as 30 days following the initiation of treatment with Natesto, with durable improvements that lasted through the duration of this study."

The study was a 90-day, randomized, open-label, dose-ranging study in hypogonadal men with sequential safety extensions out to 1 year. Natesto (125 uL/nostril, 11.0mg testosterone/dose) was self-administered using a multiple-dose dispenser either twice daily (BID) or 3 times a day (TID) for a total dose of 22.0mg or 33.0mg, respectively. Titration was performed based on blood levels to achieve the eugonadal range (300 -1050 ng/dL). Erectile function and mood were assessed at baseline (day 0), and 30 day intervals through the 90-

day treatment period using the International Index of Erectile Function (IIEF) and Positive and Negative Affect Schedule (PANAS), respectively.

Treatment with Natesto led to statistically significant improvements in each of the 5 domains of erectile function ( $F(3,813) = 83.96$   $p < .001$ ). Most of the benefit was evident by Day 30 ( $t = -9.8714$ ,  $df = 288$ ,  $p\text{-value} < .001$ ). Similar to erectile function, NTG produced clinically and statistically significant improvements in mood (PANAS) by Day 30, with continued improvements seen through study completion.

### **About Aytu BioScience, Inc.**

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on global commercialization of novel products in the field of urology. The company currently markets three products: Natesto®, the first and only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”), ProstaScint® (capromab pendetide), the only FDA-approved imaging agent specific to prostate specific membrane antigen (PSMA) for prostate cancer detection and staging, and Primsol® (trimethoprim hydrochloride), the only FDA-approved trimethoprim-only oral solution for urinary tract infections. 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 the U.S. where it is a CE Marked, Health Canada cleared product, and Aytu is conducting 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 urology products, leveraging its focused commercial team and expertise to build leading brands within well-established markets. For more information visit [aytubio.com](http://aytubio.com).

### **Forward Looking Statement**

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, including statements regarding our anticipated future clinical and regulatory events, future financial position, business strategy and plans and objectives of management for future operations, 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 collaborations. We also refer you to the risks described in “Risk Factors” in Part I, Item 1A of Aytu BioScience, Inc.’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.

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