# Natesto Spermatogenesis Study Final Results Accepted for Presentation at 'Late-Breaking' Session at the American Society for Reproductive Medicine 75th Annual Scientific Conference

# Natesto Spermatogenesis Study Data Readout Set for October 16, 2019

**ENGLEWOOD, CO / August 1, 2019 /** Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, today announced that the Natesto Spermatogenesis Study results have been accepted for presentation as a "Late-Breaking Abstract" by the American Society for

Reproductive Medicine (ASRM). The study results will be presented at the 75<sup>th</sup> ASRM Scientific Congress & Expo in Philadelphia, PA October 12-16, 2019.

The Natesto Spermatogenesis Study results have been submitted in abstract form to ASRM, and complete results will remain embargoed until the date of the presentation, which is October 16, 2019.

Dr. Ranjith Ramasamy, MD, Associate Professor and Director of Reproductive Urology at the University of Miami School of Medicine and the study's principal investigator, will present the data in conjunction with Dr. Thomas Masterson, MD, Fellow in Reproductive Urology at the University of Miami School of Medicine.

Late-breaking abstracts highlight novel and practice-changing studies and will be presented at ASRM's "Late-Breaking Abstract" session beginning at 10:45 AM ET on Wednesday, October 16, 2019. The Natesto Spermatogenesis Study is one of only six abstracts accepted for presentation by ASRM. Abstracts are accepted for presentation based on the impact of the study findings.

Following the presentation, the results of the Natesto Spermatogenesis Study will be published in abstract form in the Abstract Supplement to the journal *Fertility and Sterility*.

The Natesto Spermatogenesis Study is investigating the impact of Natesto, the only FDA approved, nasally-administered testosterone treatment, on sperm parameters. This Phase IV, single-site, prospective study is evaluating hypogonadal men, ages 18 to 55, completing a six-month treatment period with Natesto to restore clinically low serum testosterone levels with the goal of maintaining sperm concentration, motility, and total motile sperm count.

Interim results presented to date demonstrate that almost all subjects completing the sixmonth treatment period not only had serum testosterone levels return to the normal range, but all measures of semen parameters including sperm concentration, sperm motility, and total motile sperm count (TMSC) remained unchanged through three months and six months of therapy. No additional information regarding the results from the Natesto Spermatogenesis Study will be available until the data are released on October 16, 2019.

# **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<sup>™</sup>, the only FDA-approved oral spray prescription sleep aid. ZolpiMist is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Aytu also acquired exclusive U.S. commercial rights to Tuzistra® XR, the only FDAapproved 12-hour codeine-based antitussive syrup. Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in a patented, extendedrelease oral suspension. Additionally, Aytu is developing MiOXSYS<sup>®</sup>, 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.

### **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/554206/Natesto-Spermatogenesis-Study-Final-Results-Accepted-for-Presentation-at-Late-Breaking-Session-at-the-American-Society-for-Reproductive-Medicine-75th-Annual-Scientific-Conference