Aytu BioScience Announces Positive Clinical Results from Natesto(R) Spermatogenesis Study

Phase IV, Investigator-Initiated Study is First to Conclusively Show that a Testosterone Replacement Therapy (TRT) Maintains Key Fertility Measures in Men with Low T

Natesto Increased Serum Testosterone and Improved Hypogonadal Symptoms While Simultaneously Maintaining Semen Parameters and Gonadotropin Hormones in Patients Treated for Six Months

ENGLEWOOD, CO / October 17, 2019 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, announced the presentation of data from the Natesto Spermatogenesis Study as part of the "Late Breaking" Abstract Session at the 75th Annual American Society for Reproductive Medicine (ASRM) Scientific Conference today in Philadelphia, PA. This presentation was one of only six abstracts accepted as part of this session.

The study's investigators, as presented on Wednesday, October 16, 2019, concluded that men treated with Natesto for hypogonadism for six months, maintained their semen parameters while increasing serum testosterone levels and improving hypogonadal symptoms. This is the first such study to demonstrate conclusively that a testosterone replacement therapy (TRT) maintains key fertility parameters in hypogonadal men.

The company is now positioned to exclusively target and treat the approximately 12% of men under age 40 with low testosterone that are still in their 'family formation' years.

The investigator-initiated trial, designed to study the impact of nasally-administered Natesto on preservation of fertility parameters, is being conducted at the University of Miami's Department of Urology, under the direction of principal investigator Ranjith Ramasamy, MD, the department's Director of Reproductive Urology. This single-site, prospective study has evaluated hypogonadal men, ages 18 to 55, completing six months of treatment with Natesto to restore clinically low serum testosterone (T) levels with the goal of maintaining sperm concentration, motility, and total motile sperm count.

Dr. Ramasamy presented the entirety of the data to date, both three-month and six-month timepoints. In total, 55 men were eligible and enrolled in the trial. Of the 55 who enrolled, 44 patients have completed the three-month treatment period. Thirty-three patients have completed the six-month treatment period.

Among the patients completing the trial, mean T increased from 230 (62) to 605 (278) ng/dL ($p=0.005$). Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) remained within

the normal range (2-5 IU/mL).

Most importantly, mean semen parameters remained unchanged:

Semen Parameter	Baseline (SD)	3 Months (SD) n = 44	6 Months (SD) n = 33
Sperm Concentration (million/cc)	31.9 (21.8)	26.2 (19.6)	24.5 (15.8)
Sperm Motility (%)	52.6% (12.0)	50.2% (19.2)	51.6% (15.2)
Total Motile Sperm Count (million)	47.1 (46.1)	42.4 (61.4)	34.1 (24.1)

Additionally, there was improvement across all domains of erectile function including libido and overall sexual satisfaction, as well as improvement in overall energy, which are common hypogonadal symptoms.

Low testosterone (low T) affects around 12% of men under age 40, and prescriptions for testosterone replacement therapy (TRT) to men of reproductive age are increasing. As demonstrated in clinical studies, commonly prescribed TRT as gels, patches, injections and pellets are long-acting and can cause azoospermia in up to 65% of men.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, “These data conclusively demonstrate, across the largest cohort yet, that men treated with Natesto are able to maintain their fertility as evidenced by no mean change in the measured semen parameters. For the first time, a testosterone replacement therapy has been proven to increase serum testosterone while actually maintaining sperm concentration, motility, and total motile sperm count. This clearly distinguishes Natesto from all other testosterone replacement therapies and can create a clinical paradigm shift in the treatment of hypogonadism and potentially across the spectrum of male reproductive health.”

Mr. Disbrow continued, “With these data now formally presented and planned for publication, we believe we are primed to introduce these data to a broader audience of clinicians, payors, regulators, and others in expanding the use of Natesto. Additionally, in conjunction with our partners at Acerus Pharmaceuticals, we will consider our options with respect to Natesto product labeling claims as it relates specifically to these data and potentially future data sets relating to preservation of fertility parameters.”

The full treatment period for this investigator-initiated trial is six months. Complete data from the three-month and six-month timepoints were presented by Dr. Ramasamy and will now be submitted for peer review and subsequent publication.

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, and 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 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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