

Aytu BioScience Announces Publication of MiOXSYS® Data Demonstrating Clinical Utility in Diagnosing Male Infertility

Data Establishes a Clear Protocol for Reproducible Sampling and a Clinical Cut-Off Value for Distinguishing Infertile Men

ENGLEWOOD, Colo., Nov. 17, 2016 — Aytu BioScience, Inc. (OTCQX: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products in the field of urology, today announced that clinical data demonstrating the reproducibility and reliability of its novel infertility diagnosis platform MiOXSYS™ has been published in the peer-reviewed, scientific journal *Reproductive BioMedicine Online*. The data establish a clear protocol for reproducible sampling and a clinical cut-off value for distinguishing infertile men from healthy ones.

In the article titled, “Diagnostic application of oxidation-reduction potential assay for measurement of oxidative stress: clinical utility in male factor infertility,” researchers used MiOXSYS to compare the semen of control volunteers versus infertile patients for signs of oxidative stress (OS) by measuring sORP (static oxidation-reduction potential), which directly measures the balance of harmful reactive oxygen species versus antioxidants. They found a significant difference in sORP between control volunteers (1.59 ± 0.29 mV/ 10^6 sperm/ml) versus infertile volunteers (6.22 ± 1.10 mV/ 10^6 sperm/ml) ($P = 0.004$). This difference was even more significant in the subset of infertile individuals presenting with varicocele ($P = 0.0003$).

The variability of the MiOXSYS readings was also analyzed to assess reproducibility across multiple users. The coefficients of variation for three independent users of the MiOXSYS platform were 7.98%, 5.72%, and 11.96%, with an average difference between any two replicates of < 0.1 mV/ 10^6 sperm/ml. Variability analysis between users yielded a coefficient of variation of 3.61%, with no statistically significant difference between the three users’ readings. This reproducibility confirms the suitability of MiOXSYS for broad use in the clinical setting.

The optimal cut-off value to diagnose oxidative stress damage of sperm cells was calculated using a ROC curve analysis. An sORP value of 1.36 mV/ 10^6 sperm/ml resulted in a test accuracy rate of 75%, specificity of 83%, and positive predictive value of 85%. There was a strong, statistically significant, inverse correlation between sORP and all major parameters of male factor infertility, specifically sperm concentration, total sperm count, motility, and morphology. The significance of this inverse correlation is that as the sORP reading increased, all fertility parameters declined proportionally, again confirming the clinical validity of diagnosing male infertility using MiOXSYS.

Lead author and Director of Research at the American Center for Reproductive Medicine at the Cleveland Clinic, Ashok Agarwal, Ph.D., wrote, “This ORP test is able to assess OS directly in semen samples, thus potentially making it a better indicator of OS in male infertility than currently used single markers such as reactive oxygen species, total antioxidant capacity, or malondialdehyde. This test also overcomes many of the limitations of these other assays, which are tedious and time consuming, require special technical skills, and need large sample volumes.”

Dr. Agarwal continued, “Given the high sensitivity and predictive value of our preferred seminal sORP cut-off of 1.36 mV/10⁶ sperm/ml, we believe that ORP testing will be clinically useful in identifying OS in men at risk for infertility that would otherwise go undetected with a routine semen analysis.”

Josh Disbrow, Chief Executive Officer of Aytu BioScience, Inc., stated, “This study adds to the growing body of clinical evidence supporting the potential of MiOXSYS to diagnose male factor infertility due to oxidative stress. This validates our belief that the quick and easy MiOXSYS system has the potential to fill a clinical gap in the assessment of semen health. Equipping fertility clinics and andrology laboratories with this additional tool to aid in their diagnosis of male infertility will enable clinicians to employ the proper strategies to improve a patient’s semen quality and overall fertility. The MiOXSYS system is already CE Marked and commercialized abroad, and Aytu is actively working to move MiOXSYS through the U.S. FDA approval process and into the U.S. market.”

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.

For Investors & Media:

PCG Advisory Group

Stephanie Prince, Managing Director
sprince@pcgadvisory.com
(646) 762-4518

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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.

To view the original version on PR Newswire,
visit:<http://www.prnewswire.com/news-releases/aytu-bioscience-announces-publication-of-mioxsys-data-demonstrating-clinical-utility-in-diagnosing-male-infertility-300364964.html>

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