Aytu BioScience Presents Clinical Findings for its MiOXSYS® System at 33rd Annual Meeting of the European Society of Human Reproduction and Embryology

ENGLEWOOD, Colo., July 5, 2017 — Aytu BioScience, Inc. (OTCQX: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products in the field of urology, today announced seven presentations at the European Society of Human Reproduction and Embryology (ESHRE) meeting in Geneva, Switzerland. The presentations showcased new clinical findings that further validate and expand the potential utility of its MiOXSYS® System as an advanced diagnostic test for assessing oxidative stress in human semen, which is broadly implicated as a major cause of idiopathic male infertility.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, “These latest research findings continue to add to the clinical and scientific evidence supporting use of our MiOXSYS® System, which we’ve already demonstrated to be a useful clinical tool for assessing oxidative stress levels in semen as it relates to male infertility. These seven presentations at ESHRE, presented by leading andrologists and urologists from infertility centers around the world, demonstrate the broad interest and significant potential for clinical use of the MiOXSYS® System as an aid in the diagnosis of male factor infertility.”

The poster presentations were as follows:

Title: ORP: A Reliable and Reproducible Method of Evaluating Oxidative Stress – A Multicenter Study
Poster Number: G17-0526
Session: 36
Presenter: Ashok Agarwal, Ph.D., Director of the Andrology Center and Director of the American Center for Reproductive Medicine at the Glickman Urological & Kidney Institute, Cleveland Clinic, Cleveland, OH
Conclusion: Although other semen parameters showed significant differences between the two centers, sORP remained consistent in both data sets individually or in combined data. This proves its reproducibility and reliability. sORP is a measure of semen quality which adds more weight to semen testing in identifying fertile from infertile semen samples.

Title: Effect of Seminal ORP Value on Embryo Quality and Clinical Pregnancy Rate
Poster Number: G17-1357
Session: Andrology
Presenter: B. Balaban, VKF American Hospital · Assisted Reproduction Unit İstanbul, Turkey
Conclusion: These findings may have important diagnostic and prognostic implications for couples experiencing male factor infertility and undergoing assisted reproductive technique (ART). Further studies are warranted to explore the mechanism of increased ORP in a subset of couples (male factor, no female factor) undergoing ART to corroborate the significance of these findings.

Title: Oxidation-Reduction Potential and Sperm DNA Fragmentation Levels in Sperm Morphologic Anomalies
Poster Number: G17-0075
Session: 36
Presenter: A. Majzoub, Urology Department – Hamad Medical Corporation, Doha, Qatar;
Conclusion: Results were obtained from semen samples of patients presenting with primary or secondary infertility and hence were not compared with a control group or with men of proven fertility. Studying the correlation between sperm morphology indices and advanced sperm function tests is important as this would help in resting the controversy surrounding its clinical implication on fertility potential. It may also provide insights for developing novel sperm selection techniques that can be utilized during assisted reproduction.

Title: Oxidation-Reduction Potential: A Valuable Tool for Male Fertility Evaluation.
Poster Number: G17-0182
Session: 4
Presenter: A. Majzoub, Urology Department – Hamad Medical Corporation, Doha, Qatar;
Conclusion: ORP measurement with the MiOXSYS® System is a simple, quick and user friendly method that can reliably measure OS in biologic samples. The significant correlation between ORP and total motile sperm count allows its use as a predictor of fertility potential.

Title: High Levels of Seminal Oxidation-Reduction Potential (ORP) in Infertile Men with Clinical Varicocele
Poster Number: G17-0995
Session: Andrology
Presenter: R. Saleh, Director, Ajyal Hospital, Sohag, Egypt
Conclusion: These findings may have important diagnostic and therapeutic implications. Further studies are warranted to explore the mechanism of increased ORP in a subset of infertile men with clinical varicocele. In addition, future studies may help determine those patients who would benefit from antioxidant therapy and/or surgical repair of varicocele.

Title: Oxidation-Reduction Potential Can Help Distinguish Semen Samples Under Oxidative Stress

Poster Number: G17-0954
Session: Andrology
Presenter: S. Roychoudhury, Assam University, Silchar, India
Conclusion: Measuring sORP can help a clinician understand if comparatively one semen sample is under higher state of oxidative stress than another.

Title: Correlation of Sperm DNA fragmentation and Seminal Oxidation Reduction Potential in Infertile Men
Poster Number: G17-0055
Session: Andrology
Presenter: H. Elbardisi, Urology Department – Hamad Medical Corporation, Doha, Qatar;
Conclusion: Sperm DNA fragmentation and seminal oxidation reduction potential should be included in assessment of male infertility. Using ORP testing can help in detecting the target patients for antioxidant therapy.

Selection of the abstracts for publication in the press program does not imply endorsement of the MiOXSYS® System by ESHRE®.

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, with a focus on products addressing vitality, sexual wellness, and reproductive health. The company currently markets two prescription products in the U.S.: Natesto®, the first and only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”) and ProstaScint® (capromab pendetide), the only FDA-approved imaging agent specific to prostate specific membrane antigen (PSMA) for prostate cancer detection and staging. 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 planning U.S.-based clinical trials in pursuit of 510k 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 growing markets. For more information visit aytubio.com. Aytu also now owns wholly-owned subsidiary Aytu Women’s Health (formerly Nuelle, Inc.), a personal health and wellness company focused on women’s sexual wellbeing and intimacy that markets Fiera, a personal care device for women that is scientifically proven to enhance physical arousal and sexual desire. Fiera is a consumer device and is not intended to treat, mitigate, or cure any disease or medical condition. For more information about the Fiera personal care device visit fiera.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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