# Aytu BioScience Presents Clinical Findings for its MiOXSYS<sup>™</sup> System at 32nd Annual Meeting of the European Society of Human Reproduction and Embryology

ENGLEWOOD, Colo., July 7, 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 it presented three posters demonstrating the potential of MiOXSYS<sup>™</sup>, Aytu's rapid *in vitro* diagnostic system for the quantitative measurement of static oxidation-reduction potential (sORP) in human semen, to be used as an aid in the diagnosis of infertility in males.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, Inc., stated, "The medical and scientific community have long understood that oxidative stress negatively impacts male fertility. At the same time, there has not been an easily accesssible, rapid, in-office option to measure oxidative strees in semen. Aytu has been committed to conducting research to potentially validate the ability of the MiOXSYS system to fill this gap."

The posters are as follows:

**Title:** Seminal fluid static oxidation-reduction potential is lower in seminal fluid that meets all WHO criteria for fertile men

Poster Number: P-012

Session: Andrology

Presenter: AlSaid, Urology Department - HMC, Doha, Qatar;

**Conclusion:** Semen that fail one or more parameters for normal semen had higher levels of oxidative stress. Abnormal morphology contributes to increasing sORP values. Semen with an

sORP value greater than 1.635mv/10<sup>6</sup> sperm/mL had a 98.6% chance of being abnormal on one or more of the semen parameters. This represents an initial clinical cut-off value for interpreting the results of the MiOXSYS System, an adjunct measure to routine semen analyses.

**Title:** Oxidation-reduction potential: A new predictor for sperm morphology in infertile men **Poster Number:** P-013

Session: Andrology

Presenter: AlSaid, Urology Department – HMC, Doha, Qatar;

Conclusion: Semen with abnormal parameters have higher levels of oxidative stress. By

measuring sORP, a cut-off value of 3.29mV/10<sup>6</sup> sperm/mL was able to reliably predict abnormal morphology. This study suggests that measuring sORP might provide users with an independent measure for confirming sperm morphology.

Title: Oxidation-reduction Potential (ORP) of Spermatozoa Selected for Intracytoplasmic

Sperm Injection (ICSI) After Exposure to Polyvinylpyrrolidone (PVP) and Hyaluronic Acid (HA) **Poster Number:** P-019

## Session: Andrology

**Presenter:** Ashok Agarwal, Ph.D., Director of the Andrology Center and Director of the American Center for Reproductive Medicine under the Glickman Urological & Kidney Institute, Cleveland Clinic

**Conclusion:** Lower levels of sORP in PVP-treated group than in the HA-treated group and the control group are novel findings and suggest that PVP might alleviate sperm oxidative stress as it contains a synthetic serum replacement that acts as a chelating agent. Our results support the continued clinical use of PVP for selection and manipulation in ICSI processes.

Selection of the abstracts for publication in the press programme does not imply endorsement of the MiOXSYS System by ESHRE<sup>®</sup>.

### 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<sup>®</sup>, the first and only FDA-approved nasal formulation of testosterone

for men with hypogonadism (low testosterone, or "Low T"), ProstaScint<sup>®</sup> (capromab pendetide), the only FDA-approved imaging agent specific to prostate specific membrane

antigen (PSMA) for prostate cancer detection, and Primsol<sup>®</sup> (trimethoprim hydrochloride), the only FDA-approved trimethoprim-only oral solution for urinary tract infections. 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 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 Investors & Media:

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### **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.

To view the original version on PR Newswire,

visit:http://www.prnewswire.com/news-releases/aytu-bioscience-presents-clinical-findings-forits-mioxsys-system-at-32nd-annual-meeting-of-the-european-society-of-human-reproductionand-embryology-300295125.html

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