Aytu BioScience Announces Availability of the MiOXSYS(R) Male Infertility Test in the United Kingdom

ENGLEWOOD, CO / May 21, 2019 / Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, today announced that MiOXSYS®, the company's first-in-class seminal oxidative stress test for the assessment of male infertility, is now available in the United Kingdom.

MiOXSYS, the Male Infertility Oxidative System, is CE marked and cleared by Health Canada, Australia's TGA, and Mexico's COFEPRIS. MiOXSYS is the first cleared advanced *in vitro* diagnostic test that assesses seminal oxidative stress, a major cause of male infertility.

According to the UK's Nation Health Service (NHS), approximately one in seven couples struggle to conceive in the UK. Over 60% of couples pay for their reproductive treatments, with one in ten spending up to £100,000 for fertility care. Among those couples unable to conceive, infertility is partially or wholly attributable to male factor infertility in approximately 50% of cases. Of those cases, male factor infertility can remain undefined in 30% to 50% of patients. A recent report estimated that the UK fertility market is worth £320 million annually and is experiencing accelerating growth.

Dr. Sheryl Homa, a leading authority on male infertility and the Scientific Director of Andrology Solutions, an independent, scientist-led clinic specializing in male fertility in the United Kingdom, commented, "We are especially pleased about the availability of the MiOXSYS System for patient care in the UK. Oxidative stress is one of the major causes of male infertility, and it is well understood that oxidative stress has negative effects on spermatozoa and is a prominent cause of sperm dysfunction as well as DNA damage. Our studies utilizing the MiOXSYS platform, which were published in *Genes* in March, and in *The World Journal of Men's Health* in May show that there was a significant increase in sperm DNA damage in semen samples that exhibited oxidative stress as measured by MiOXSYS. The severity of the pathological consequences of oxidative stress on sperm highlights the importance of accurately measuring oxidative stress as the most influential marker of sperm function."

Josh Disbrow, Chief Executive Officer of Aytu BioScience, added, "We are delighted by the acceptance of MiOXSYS in the UK and by world experts such as Dr. Sheryl Homa. The nationwide availability of MiOXSYS will allow physicians immediate access to this breakthrough diagnostic test and enable effective assessment and monitoring of male infertility patients throughout the UK."

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 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 revenue growth, 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 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.

Contact for Investors:

James Carbonara
Hayden IR
(646)-755-7412
james@haydenir.com

SOURCE: Aytu BioScience, Inc.

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