Aytu BioScience Obtains CE Marking for Company's MiOXSYS™ System for Male Infertility

Regulatory Clearance Enables Commercialization in Europe and other Key Markets

ENGLEWOOD, Colo., Jan. 12, 2016 — Aytu BioScience, Inc. (OTCQX: AYTU), a specialty healthcare company focused on commercializing treatments for urological and related conditions, today announced that it has obtained CE Marking in Europe for its MiOXSYS™ System. MiOXSYS is the company's in vitro diagnostic platform for assessing the level of oxidative stress in semen as an aid in the diagnosis of infertility in males. This regulatory clearance positions Aytu for a launch in Europe and other markets and expands Aytu's portfolio of marketed products including ProstaScint® and Primsol®.

Josh Disbrow, Chief Executive Officer of Aytu, stated, "Aytu is building a portfolio of specialized products focused on the urology market, and we aim to serve a large area of medical need with the launch of MiOXSYS. We expect MiOXSYS to be a valuable product for our urology customers given the widespread need for improved diagnosis in the field of male infertility, which accounts for approximately 40-50% of all infertility cases in the US and Europe. Semen analysis studies are already routinely conducted around the world to assess causes of infertility, and these studies often include oxidative stress assessments. Additionally, antioxidant supplementation is frequently recommended to patients by clinicians without an effective method of measuring treatment success. Now with the availability of MiOXSYS, we expect clinicians to integrate MiOXSYS into routine assessment of infertility status and monitoring of treatment effects. We look forward to launching this novel product in Europe while seeking Food and Drug Administration (FDA) approval in the United States."

A significant proportion of male infertility remains unexplained in part because of the lack of standardized tests available to clinicians and researchers to assess oxidative stress, which is well established as a leading contributing factor to idiopathic male infertility. This lack of standardization has resulted in poor implementation of semen and plasma analysis around the world.

Aytu has conducted clinical studies in male infertility with a leading center in the United States and determined that oxidation-reduction potential, the key parameter reported by the MiOXSYS system, effectively measures oxidative stress levels in semen and seminal fluid. Additional studies are now underway in the US and around the world that will determine the MiOXSYS system's performance in semen analysis as it relates to a broad range of uses in male infertility. The company expects to initiate clinical trials in the United States to enable submission of MiOXSYS to the FDA.

About Aytu BioScience, Inc.

Aytu BioScience, Inc. is a commercial-stage specialty healthcare company focused on urological and related conditions. The Company's products include FDA-approved

ProstaScint® (capromab pendetide), a radio-labeled monoclonal antibody that targets
Prostate Specific Membrane Antigen (PSMA), a protein highly expressed by prostate cancer;

as well as Primsol® (trimethoprim oral solution), the only FDA-approved oral solution of trimethoprim, the standard therapy for urinary tract infections. Aytu's strategy is to continue building its portfolio of revenue-generating urology products and late-stage development assets, leveraging its commercial team and expertise to further build those brands within well-established markets.

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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 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-obtains-ce-marking-for-comp anys-mioxsys-system-for-male-infertility-300202713.html

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