

## **Aytu BioScience Announces Study Initiation and First Patient Dosing in Prostate Cancer Clinical Study with Hybridyne Imaging Technologies for ProstaScint® in Combination with Hybridyne's ProxiScan™ Transrectal Camera**

ENGLEWOOD, Colo., June 6, 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 has begun enrollment and patient dosing in their prostate cancer study, *Detection and localization of carcinoma using high resolution transrectal gamma imaging (TRGI)*, in collaboration with Hybridyne Imaging Technologies to investigate the efficacy of Hybridyne's ProxiScan™ compact gamma cameras to detect local prostate cancer using Aytu's imaging agent ProstaScint®.

The study is now enrolling patients at Princess Margaret Cancer Centre, Canada's largest cancer treatment center, and is being led by Principal Investigator Dr. Antonio Finelli. Under the study, approximately 60 men will take part in this three-arm, open label study, including the following patient groups:

- Group 1: Patients who have rising levels of PSA (>0.05ng/ml) after radical prostatectomy treatment
- Group 2: Patients who have rising PSA (>10ng/ml) and/or abnormal digital rectal exam and have previously undergone at least one prostate biopsy that was determined to be negative for prostate cancer
- Group 3: Patients diagnosed with prostate cancer (with at least one positive prostate biopsy) and have a scheduled biopsy as part of their routine follow-up

Josh Disbrow, Chief Executive Officer of Aytu, stated, "ProstaScint remains an important product in Aytu's growing urology portfolio, and we are pleased to have this unique clinical study underway at Princess Margaret Cancer Centre to potentially expand the utility and application of ProstaScint. ProstaScint is a well established, FDA-approved imaging agent that can specifically target prostate cancer, and the clinical acceptance of ProstaScint may improve through the generation of additional clinical data examining ProstaScint's use in conjunction with ProxiScan. We look forward to progressing this study in conjunction with Hybridyne and Princess Margaret Cancer Centre, our first ProstaScint clinical collaboration outside the U.S."

ProstaScint is an FDA-approved imaging agent that specifically targets prostate specific membrane antigen (PSMA) and demonstrates high sensitivity, specificity, and accuracy. Hybridyne's high-resolution ProxiScan gamma camera utilizes cadmium zinc telluride (CZT) detector technology and is small enough for trans-rectal prostate cancer diagnosis, after the

patient is injected with an imaging agent such as ProstaScint. Combined, these technologies stand to offer additional diagnostic and prognostic assurances to urologists, ultimately increasing the quality of care for prostate cancer patients in Canada and potentially elsewhere around the world.

Additional information about the study can be found here:

<https://clinicaltrials.gov/ct2/show/NCT02786459?term=proxiscan&rank=1>.

### **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 two products: ProstaScint<sup>®</sup> (capromab pendetide), the only FDA-approved imaging agent specific to prostate cancer, and Primsol<sup>®</sup> (trimethoprim hydrochloride), the only FDA-approved trimethoprim-only oral solution for urinary tract infections. Aytu recently acquired exclusive U.S. rights to Natesto<sup>®</sup>, the first and only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”), which the company plans to launch in July 2016. 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 with and future outcomes and events under our current and potential future collaborations; 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; and our anticipated future cash position. We also refer you to the risks described in "Risk Factors" in Part I, Item 1A of Aytu BioScience, Inc.'s most recent 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-study-initiation-and-first-patient-dosing-in-prostate-cancer-clinical-study-with-hybridyne-imaging-technologies-for-prostascint-in-combination-with-hybridynes-proxiscan-transrectal-camera-300279692.html>

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