

## **Aytu BioScience Announces Study Collaboration with Hybridyne Imaging Technologies for Minimally Invasive Prostate Cancer Detection**

ENGLEWOOD, Colo., March 1, 2016 — **Aytu BioScience, Inc.** (OTCQX: AYTU), a commercial-stage specialty healthcare company focused on commercializing treatments for urological conditions, today announced that it has entered into a study agreement 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 being conducted at The Princess Margaret Cancer Centre in Toronto, Canada, and supported by Hybridyne. As part of the agreement Hybridyne will purchase ProstaScint for the study, establishing Aytu's first ProstaScint sales outside the U.S.

ProstaScint is FDA-approved and the only imaging agent that specifically targets prostate cancer cells and demonstrates high sensitivity, specificity, and accuracy. Hybridyne's high-resolution ProxiScan gamma camera utilizes cutting-edge cadmium zinc telluride (CZT) detector technology and is small enough for trans-rectal prostate cancer diagnosis, after the patient is injected with a radiopharmaceutical 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.

Josh Disbrow, Chief Executive Officer of Aytu, stated, "Prostate cancer is the second leading cause of cancer death among men, marking a great need for better detection in both newly diagnosed, high-risk patients and patients with biochemical recurrence. We are excited to initiate this study with Hybridyne and Princess Margaret Cancer Centre as it is Aytu's first clinical collaboration with ProstaScint outside the U.S. This collaboration demonstrates our strong interest in gaining clinical acceptance of ProstaScint around the world while developing additional clinical data supporting ProstaScint's use. ProstaScint is the only FDA-approved agent that can specifically target prostate cancer, while ProxiScan has demonstrated highly detailed trans-rectal image quality in prostate cancer. Both products have strong potential roles to play in the identification and treatment of both new and recurrent prostate cancer patients, and we look forward to seeing the results of this clinical study following study completion."

The planned study *Detection and localization of carcinoma using high resolution transrectal gamma imaging (TRGI)* is being led by Principal Investigator Dr. Antonio Finelli. The study is being conducted at Princess Margaret Cancer Centre, Canada's largest cancer treatment center.

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

### **About Aytu BioScience, Inc.**

Aytu BioScience is a commercial-stage specialty healthcare company focused on global commercialization of novel products in the field of urology. Aytu's current portfolio of commercial and late-stage urology products addresses prostate cancer, urinary tract infections, male infertility and male sexual dysfunction, and the company plans to expand into other urological indications for which there are significant medical needs. The company currently markets ProstaScint<sup>®</sup> (capromab pendetide), the only radio-labeled monoclonal antibody that targets prostate specific membrane antigen (PSMA), a protein highly expressed by prostate cancer cells. ProstaScint is FDA-approved as an imaging agent for use in both newly diagnosed, high-risk prostate cancer patients and patients with recurrent prostate cancer. Aytu also markets Primsol<sup>®</sup> (trimethoprim hydrochloride) – the only FDA-approved trimethoprim-only oral solution for urinary tract infections. Additionally, Aytu markets the CE Marked MiOXSYS<sup>™</sup> System outside the US and is conducting US-based clinical trials, following which the company expects to receive 510k de novo medical device clearance. The MiOXSYS System is a novel, rapid semen analysis system with the potential to become a standard of care in the diagnosis and management of male infertility. MiOXSYS is the only rapid test for assessing oxidative stress in semen and seminal plasma, a leading contributor of idiopathic male infertility. 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 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-collaboration-with-hybridyne-imaging-technologies-for-minimally-invasive-prostate-cancer-detection-300228301.html>

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