iCAD Launches Post-Market Study of Intra-Operative Radiation Therapy to Treat Early Stage Breast Cancer

Study Will Compare Xoft® Intra-Operative Radiation Therapy with External Beam Radiation Therapy

NASHUA, NH (March 15, 2012) – iCAD, Inc. (Nasdaq: ICAD), an industry-leading provider of advanced image analysis, workflow solutions and radiation therapy for the early identification and treatment of cancer, announced today the launch of a post-market study to assess the safety and efficacy of the company’s FDA-cleared Xoft Axxent® eBx™ System when used for single-fraction, intra-operative radiation therapy (IORT) at the time of lumpectomy for early stage breast cancer. A historical comparison will be made to the current standard of care, external beam radiation therapy (EBRT). The announcement was made during the 29th Annual Miami Breast Cancer Conference where iCAD is showcasing the Xoft System.

"While many breast surgeons and radiation oncologists have already experienced the benefits of treating early stage breast cancer patients with a single dose of radiation during lumpectomy, external beam after lumpectomy remains the current standard of care, subjecting many patients to weeks of daily radiation treatments," said Helena Chang, MD, PhD, University of California Los Angeles and co-principal investigator for the study. “This study will enable users of the Xoft System to treat patients with suitable early stage breast cancer under a standardized IORT protocol and follow long-term patient outcomes in a controlled manner.”

The study, “A Safety and Efficacy Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft Axxent eBx® System at the Time of Breast Conservation Surgery for Early-Stage Breast Cancer,” is a prospective, multi-center, historical control trial. Researchers plan to enroll up to 1,000 patients at as many as 50 study sites across the U.S. and Europe. Study subjects will be followed for 10 years after treatment to determine the safety and efficacy of IORT with the Xoft System, and interim data will be collected on an annual basis. The studies will also assess cosmetic outcomes and quality of life for subjects treated with Xoft IORT.

“We believe the results from this study will further validate existing data showing IORT to be as safe and effective as external beam radiation, positioning the Xoft System as a treatment alternative that may be delivered more conveniently while improving a patient’s quality of life,” said Ken Ferry, President and CEO of iCAD. “Compliance rates with EBRT vary widely between different populations based on proximity to care, length of treatment, and other factors. The use of Xoft’s technology significantly expands patient access to this potentially life-saving treatment. This study underscores iCAD’s continued commitment to advancing the field of cancer detection and treatment.”

iCAD is currently seeking investigative sites to participate in this study. For more information contact Michael Patz, Director of Clinical Affairs at iCAD at mpatz@icadmed.com or visit www.clinicaltrials.gov.

About Xoft
The Xoft eBx® Electronic Brachytherapy System from iCAD is an isotope-free (non-radioactive) radiation treatment cleared by the FDA for use anywhere in the body, including for the treatment of early stage breast cancer, endometrial cancer and skin cancer. The Xoft System utilizes a proprietary miniaturized x-ray as the radiation source that delivers precise treatment directly to cancerous areas while sparing healthy tissue and organs. Xoft eBx® can be administered as a single course of radiation therapy during surgery in the form of intraoperative radiation therapy (IORT) or in the form of partial breast irradiation (APBI). The Xoft System does not require a shielded environment and the system’s relatively small size and mobility allow for it to be used in virtually any clinical setting. For more information about Xoft visit www.xoftinc.com

About iCAD, Inc.
iCAD, Inc. is an industry-leading provider of advanced image analysis, workflow solutions and radiation therapies for the early identification and treatment of cancer. iCAD offers a comprehensive range of high-performance, upgradeable Computer-Aided Detection (CAD) systems and workflow solutions for mammography, Magnetic Resonance Imaging (MRI) and Computed Tomography (CT). iCAD recently acquired Xoft, Inc., developer of the Axxent® eBx® electronic brachytherapy system (eBx). Axxent uses isotope-free, miniaturized X-ray tube
technology and is FDA-cleared for treatment of early stage breast cancer, skin cancer and endometrial cancer. The Axxent System is also cleared for use in the treatment of other cancers or conditions where radiation therapy is indicated including Intraoperative Radiation Therapy (IORT). For more information, call (877) iCADnow or visit www.icadmed.com.

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