12 MONTH FOLLOW-UP DATA FOR ISOTOPE-FREE BREAST IORT PRESENTED AT ASBS MEETING

Research Demonstrates Excellent Results for IORT Treatment Using Electronic Brachytherapy

LAS VEGAS, April 28, 2010 – Utilization of the FDA cleared Axxent® Electronic Brachytherapy, eBx™, System to deliver intraoperative radiation therapy (IORT) is growing as clinical experience demonstrates the isotope-free cancer treatment platform is a patient and physician friendly alternative. Xoft will showcase a variety of IORT oncology applications at the 11th Annual Meeting of the American Society of Breast Surgeons here, April 28-May 2, 2010.

In the study, “Twelve-Month Follow-Up Results of a Trial Utilizing Xoft Axxent Electronic Brachytherapy to Deliver Intraoperative Radiation Therapy for the Early Stage Breast Cancer,” researchers enrolled 11 patients in an IRB approved IORT treatment protocol and reported oncologic, cosmetic and mammographic outcomes at one year post-IORT. The 12-month results suggest that IORT utilizing Xoft’s Electronic Brachytherapy is emerging as a novel, patient and physician friendly alternative to Whole Radiation Therapy (WBRT) as well as APBI in a selected group of patients with early breast cancer. This work is presented in ASBS Poster #66 by Olga Ivanov, M.D., breast surgeon and medical director for Little Company of Mary’s Comprehensive Breast Health Center.

“When compared to other radiation techniques, IORT is emerging as a feasible, well-tolerated alternative to post-surgical APBI and whole breast radiation therapy. In this trial, eBx was utilized for the first time to successfully deliver 20 Gy of radiation intra-operatively to 11 patients. At a mean follow-up of 12 months, overall results are extremely encouraging with excellent scores achieved in cosmesis and patient satisfaction. While long-term follow-up will continue, no recurrences have been observed to date,” said Dr. Ivanov.

“In addition to the potential clinical benefits, from a patient’s perspective the nominal extra time spent by the radiation oncologist and surgeon in the OR will negate the often difficult logistics of WBRT or APBI,” added Dr. Ivanov. “The use of IORT may also obviate the need for mastectomy in patients who cannot travel to a radiation treatment center for therapy where it has been shown that an increase in travel distance to a radiation facility decreases the chances of a woman receiving treatment. In one study only 51% of women completed prescribed therapy if they lived more than 75 miles from the radiation facility.”

IORT is a radiation therapy technique where a concentrated dose of radiation is delivered to a cancerous tumor site during surgery after the tumor is removed. Because the target and normal tissues can be clearly identified during surgery, IORT may increase targeting accuracy, thereby increasing dose to the target and reducing dose to critical structures. For breast IORT, the shorter treatment time is
generally more convenient for patients than the seven-week course of external beam-therapy, and may increase patient compliance.

The Xoft eBx System uses a miniaturized X-ray source instead of a radioactive isotope to deliver radiation to the breast from within a balloon catheter. The low energy and rapid dose fall-off of the electronic source permit treatment in typical operating rooms, with minimal shielding required. Lightweight and mobile, the system can be moved easily between multiple ORs.

Available for treatment of early stage breast cancer, endometrial cancer, and skin cancer, the Axxent eBx System is also FDA-cleared for IORT (intra-operative radiation therapy). As a platform technology, the Axxent System is designed to deliver non-radioactive therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue. Utilizing a proprietary miniaturized X-ray source and robotic controller, the system can be used to deliver radiation in minimally shielded therapeutic settings. Treatment can be performed without the need for a shielded room, allowing the radiation oncologist and other medical personnel to be present during treatment delivery which minimizes patient anxiety.

“We are very pleased with the strong interest in and growing adoption of multi-disciplinary approaches for use of Electronic Brachytherapy to deliver IORT for breast and other cancers,” said Michael Klein, president and CEO of Xoft. “We are encouraged that studies reinforce the clinical value of IORT applications for eBx, and strongly believe that providing a safe and portable method to deliver treatment to the lumpectomy cavity as soon as the tumor is removed and before any remaining cells have a chance to reproduce, is extremely important to improving patient care.”

About Xoft, Inc.
Xoft develops Electronic Brachytherapy (eBx) systems based upon miniaturized X-ray tube technology for the practice of radiation oncology in virtually any clinical setting, eliminating the need for heavily shielded environments. The Axxent® treatment platform provides a therapeutic dose of radiation directly to the region at risk with minimal radiation exposure to surrounding healthy tissue and without the complex handling, resource logistics and costs associated with using radioactive isotopes. Xoft aligns with the Nuclear Regulatory Commission’s (NRC) directive to seek alternatives for radioactive medical isotopes. Commercially available for treatment of early stage breast cancer, skin cancer and endometrial cancer indications, the Axxent Electronic Brachytherapy System is also cleared for use in the treatment of other cancers or conditions where radiation therapy is indicated. For information, visit www.xoftinc.com.

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