Accelerated Partial Breast Irradiation with Brachytherapy Achieves Excellent Long-Term Toxicity and Cosmetic Outcomes

- *PROMIS registry study data supports an update of guidelines and clinical adoption of APBI with brachytherapy for women with early-stage breast cancer* -

- *Results announced during ASTRO 2015* -

SAN ANTONIO – October 20, 2015 – Researchers today presented toxicity and cosmesis results of a long-term retrospective study of U.S. breast cancer patients demonstrating that women receiving accelerated partial breast irradiation (APBI) via interstitial multicatheter brachytherapy experienced low rates of long-term toxicity and excellent cosmetic outcomes. Previous presentations and publications of this retrospective study data also suggest that many women, including those younger than 50 years of age and those with DCIS, could be appropriate candidates for APBI brachytherapy. The latest study results were presented at the American Society for Radiation Oncology (ASTRO) Annual Meeting, taking place in San Antonio from October 18-21.

“These data contribute to the significant body of evidence – including phase II studies, the SAVI Collaborative Research Group Registry and the ASBrS MammoSite Registry – as well as the highly compelling level one evidence unveiled yesterday by the GEC-ESTRO working group that support the clinical utility of APBI brachytherapy in patients with low risk breast cancer,” said Robert Kuske, M.D., presenting study author and radiation oncologist at Arizona Breast Cancer Specialists. “ABPI brachytherapy is one of the most studied treatments in breast cancer, and we now have evaluated this modality in more patients than were included in the studies that allowed us to evolve from mastectomy to breast conserving surgery. We are optimistic that APBI brachytherapy will become a standard option for a broad patient population, including women age 40 and above and those with DCIS.”

The PROMIS (Pooled Registry of Multicatheter Interstitial Sites) registry is a multicenter retrospective review evaluating outcomes of APBI brachytherapy in 1,372 patients between 1997 and 2013, with a median follow-up period of 6.8 years. Participating centers included Arizona Breast Cancer Associates, University of Wisconsin, William Beaumont Hospital, Gamma West Cancer Services and the University of California Los Angeles.

Patients with Stage T1-2 (pathologic size less than 3 cm), N0, and N1 had breast conserving surgery followed by APBI with interstitial multicatheter brachytherapy. In the study population, 17% received chemotherapy and 69% received endocrine therapy. Cosmesis, toxicities and subsequent mastectomy rates were evaluated at yearly intervals.

APBI with brachytherapy was associated with excellent cosmetic outcomes, low toxicity and mastectomy rates. Results included good or excellent cosmesis in more than 90% of patients, with only a 2% subsequent mastectomy rate.

Data from the PROMIS registry study have been presented several times previously, most recently in the April issue of *Annals of Surgical Oncology*, the official journal of the Society of Surgical Oncology and the American Society of Breast Surgeons. Results showed the ten-year actuarial risk of breast cancer recurrence was 7.6%, which compares favorably to recurrence rates after WBI or mastectomy.

“It is an exciting time for breast cancer specialists and patients as rapidly expanding data from European and U.S. studies establish APBI brachytherapy as an accepted treatment option for women with early stage breast cancer,” noted Mitchell Kamrava, M.D., study co-author and assistant clinical professor, Department of Radiation Oncology, University of California Los Angeles Jonsson Comprehensive Cancer Center. “These compelling data from the PROMIS registry and GEC-ESTRO clinical trial offer substantial real-world evidence supporting APBI brachytherapy. We expect that current treatment guidelines will evolve based on these studies.”

About APBI Brachytherapy

Accelerated partial breast irradiation with brachytherapy (APBI brachytherapy) is a shortened course of high-dose radiation therapy for early-stage breast cancer patients where radiation is delivered directly into the tumor bed. APBI brachytherapy is delivered as part of breast conservation therapy (BCT), which consists of lumpectomy surgery followed by radiation.

The traditional approach for radiation therapy as part of BCT has been whole breast irradiation (WBI). A full course of WBI exposes the entire breast and surrounding critical structures to radiation and requires daily treatments for three to seven weeks where radiation is delivered from outside the breast. APBI brachytherapy, which was developed to address several issues with WBI, delivers radiation only to the lumpectomy cavity and immediate surrounding tissue.

APBI brachytherapy offers three significant advantages over WBI: a reduction in total radiation exposure, particularly to the heart, lungs and skin, the preservation of future treatment options and a reduced treatment time. Since its introduction in the late 1990s, more than 100,000 women in the U.S. have received different types of APBI brachytherapy.

About Elekta

Elekta is a human care company pioneering significant innovations and clinical solutions for treating cancer and brain disorders. The company develops sophisticated, state-of-the-art tools and treatment planning systems for radiation therapy, radiosurgery and brachytherapy, as well as workflow enhancing software systems across the spectrum of cancer care. Stretching the boundaries of science and technology, providing intelligent and resource-efficient solutions that offer confidence to both health care providers and patients, Elekta aims to improve, prolong and even save patient lives.

Today, Elekta solutions in oncology and neurosurgery are used in over 6,000 hospitals worldwide. Elekta employs around 3,800 employees globally. The corporate headquarters is located in Stockholm, Sweden, and the company is listed on NASDAQ Stockholm. Website: www.elekta.com.

About Cianna Medical, Inc.

Cianna Medical develops, manufactures and markets innovative medical technologies that reduce costs, improve quality, and reduce the burden breast cancer treatment places on women and their families. Its SAVI® technologies are FDA-cleared and address unmet needs in the delivery of radiation therapy, tumor localization and surgical guidance.

The market leading SAVI® breast brachytherapy applicator delivers a highly targeted, personalized dose of radiation to just the area that needs it most, preventing radiation exposure

to healthy tissue. This treatment approach preserves future treatment options and enables women to undergo a significantly shorter treatment period (four or five days versus the three to seven weeks required for traditional whole breast irradiation) while limiting radiation-induced side effects.

The SAVI SCOUT® surgical guidance system offers surgeons a non-radioactive method for targeting tissue for removal during lumpectomy and excisional biopsy procedures.

For more information, call 866-920-9444 or visit www.ciannamedical.com.

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