

**Phase III Data Published in *The Lancet* Show Accelerated Partial Breast Irradiation with Multicatheter Brachytherapy is Clinically Equivalent to Whole Breast Irradiation in Early Stage Cancer**

- *Results show positive toxicity and side effect trends* -
- *Multicenter prospective study is largest ever to evaluate targeted and abbreviated accelerated treatment modality in breast conserving surgery* -

SAN ANTONIO – October 19, 2015 – Today, results from a large prospective, randomized, multicenter phase III study comparing accelerated partial breast irradiation (APBI) with interstitial multicatheter brachytherapy to whole breast irradiation (WBI) were published in [The Lancet](#). Findings from the study, conducted by Groupe Européen de Curiethérapie European Society for Therapeutic Radiology and Oncology (GEC-ESTRO), demonstrate that APBI brachytherapy has an equivalent rate of overall survival, disease-free survival and local and regional cancer control as compared to traditional WBI after breast conserving surgery for selected patients with stage 0-II breast cancer. The data also demonstrate positive trends for APBI over WBI with regard to skin toxicity and fibrosis as well as other adverse events including breast pain.

The manuscript was published online and in print by *The Lancet* following an initial presentation of primary efficacy data from the GEC-ESTRO trial at the American Society for Radiation Oncology (ASTRO) Annual Meeting this morning.

“My colleagues and I are pleased to share these important data which further validate the established and growing body of clinical evidence supporting APBI with brachytherapy as a safe and effective alternative to whole breast irradiation,” said Csaba Polgár, M.D., Ph.D., M.Sc., Professor and Head of the Radiotherapy Center at the Hungarian National Institute of Oncology, Budapest, Council Member GEC-ESTRO and co-lead study author. “In addition to establishing that APBI brachytherapy provides equivalent clinical results to whole breast irradiation, these milestone findings are the first to offer the level one clinical evidence necessary to fundamentally alter the treatment paradigm for women aged 40 years and above with early stage breast cancer.”

The primary objective of the GEC-ESTRO trial was to assess the role of APBI brachytherapy alone compared to whole breast irradiation with boost in a defined group of patients with invasive (stage I-IIA) breast cancer or ductal carcinoma in situ (DCIS; stage 0) who underwent breast-conserving surgery. Researchers evaluated a total of 1,184 patients aged 40 years and above who were randomized to a standardized treatment arm (WBI, n=551) or an investigational treatment arm (APBI, n=633). Median age of enrolled patients was 62 years with nearly half less than 60 years. Patients received follow-up examinations every three months initially and annually after 60 months. The median follow up in the study was 6.6 years.

Study results confirm that adjuvant APBI with brachytherapy after breast conserving surgery is not inferior to adjuvant WBI with boost for selected patients with early breast cancer, with equivalent local recurrence observed with both treatment modalities. At five-year follow-up, nine patients treated with APBI and five patients treated with WBI had a local recurrence, equating to cumulative recurrence rates of 1.44% and 0.92% (p=0.42) respectively. No significant difference in regional recurrence was observed between groups. The incidence of salvage surgery was low with mastectomy being performed in one APBI patient and zero WBI patients, and

lumpectomy being performed in two APBI patients and four WBI patients. Five-year overall survival was 95.55% with WBI versus 97.27% for APBI, with no observed difference in breast cancer related mortality between treatment arms. Efficacy of APBI at five years was independent of age and tumor characteristics.

A low incidence of all serious late side effects (around 3% in both arms) was noted. The five-year risk of grade 2-3 late side effects to the skin was 3.2% with APBI versus 5.7% with WBI ( $p=0.08$ ) and five-year risk of grade 2-3 subcutaneous tissue late side effects was 7.6% versus 6.3% ( $p=0.53$ ). The risk of severe (grade 3) fibrosis at five years was 0% with APBI and 0.2% with WBI ( $p=0.46$ ). The risk of grade 2-3 breast pain was significantly lower in patients treated with APBI (1.14% vs 3.17%;  $p=0.0389$ ). No grade 4 late side effects were reported and no difference in mastectomy rates was observed between arms.

The multicenter study was conducted at 16 leading medical centers in Austria, the Czech Republic, Germany, Hungary, Poland, Spain and Switzerland.

“Early stage breast cancer remains a disease with high unmet medical needs that places an enormous physical, emotional and economic burden on women, families and healthcare systems,” noted Prof. Vratislav Strnad, M.D., Ph.D., chair of the GEC-ESTRO Breast Cancer Working Group and radiation oncologist at the Department of Radiation Oncology of University Hospital, Erlangen, Germany. “These robust data, representing the largest randomized prospective study of its type ever conducted to date, confirm previous studies that show patients treated by a short course of APBI with multicatheter brachytherapy experience equivalent rates of recurrence, disease-free survival, overall survival and toxicity compared to those receiving a traditional longer course of external whole breast irradiation. We anticipate these data will drive significant changes in how clinicians approach early stage breast cancer treatment in patients from 40 years and above and place APBI multicatheter brachytherapy as an accepted standard alternative to whole breast irradiation.”

### **About APBI with 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 the Nordic Exchange under the ticker STO:EKTAB. Website: [www.elekta.com](http://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<sup>®</sup> technologies are FDA-cleared and address unmet needs in the delivery of radiation therapy, tumor localization and surgical guidance.

The market leading SAVI<sup>®</sup> 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<sup>®</sup> 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](http://www.ciannamedical.com).

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