



Clinical Data for Carl Zeiss Meditec's INTRABEAM Targeted Intraoperative Radiotherapy System for Breast Cancer to be Presented at ASCO 2010

- Ten-year TARGIT-A International Multicenter Study Investigates INTRABEAM Single-Dose Partial Breast Irradiation Against Standard Three- to Six-week Whole Breast Irradiation -

JENA, Germany/DUBLIN, CA – 26 May 2010. Carl Zeiss Meditec announced that the TARGIT-A (TARGeted Intra-operative radiation Therapy) multicenter clinical trial that used the INTRABEAM® device, will be the subject of a late-breaking presentation at the American Society of Clinical Oncology's (ASCO's) 46th Annual Meeting in Chicago, IL. This randomized controlled trial was designed to assess the equivalency of targeted intraoperative radiotherapy with a single-dose using INTRABEAM® against standard three to six week external beam radiotherapy after breast conserving surgery in women 45 years and over with invasive ductal carcinoma. TARGIT-A is the first clinical trial conducted in the field of intra-operative radiotherapy in breast cancer to be reported.¹

The ASCO presentation titled, "Safety and efficacy of targeted intraoperative radiotherapy (TARGIT) for early breast cancer: First report of a randomized controlled trial at 10 years maximum follow-up," will be presented by principal investigator, Michael Baum, MD of University College London at the ASCO meeting on June 7, 2010. In April 2010, TARGIT-A completed accrual of 2,232 breast cancer patients at 28 centers in nine countries throughout Europe, North America and Asia.

"We hope that the clinical results for the TARGIT procedure, in which INTRABEAM is the enabling technology, tested in this international clinical trial, might have a profound effect on the thinking within the clinical community," said Ludwin Monz, CEO of Carl Zeiss Meditec. "Carl Zeiss Meditec is committed to pioneering innovative medical technologies providing significant medical benefits to patients. Moreover, we believe that INTRABEAM has the potential to change the manner in which certain types of breast cancers are treated in the near future."

INTRABEAM®, a miniature electron beam-driven X-ray source, is used to provide low-energy X-rays directly into the area of interest immediately after excision of the tumor, to provide intraoperative radiotherapy accurately targeted to the tissues at risk of local recurrence. The TARGIT-A clinical trial seeks to determine whether a single, localized fraction of INTRABEAM® targeted intraoperative radiotherapy is equivalent to standard external beam radiotherapy, which uses linear accelerators to irradiate the entire breast externally during a three to six week period of consecutive treatments.

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"TARGIT-A is the longest-running breast cancer study of its kind and it is also the first randomized partial breast irradiation study to be reported," said co-principal investigator, Prof. Baum, who pioneered the TARGIT approach along with Jayant S. Vaidya and Prof. Jeffrey Tobias. "These study results, representing a decade of interdisciplinary clinical experience by leading surgeons, radiation-oncologists scientists and physicists, has the potential of changing the way we think about the primary management of early breast cancer as well as financial considerations that impact the health care system."

There are several potential benefits to INTRABEAM® single-dose TARGIT treatment, including:

- A significant reduction in radiation treatment time for the patient.
- Improved access to radiation therapy for patients in rural areas and developing countries.
- Potentially, less toxicity related to external beam radiotherapy.
- Minimized exposure to healthy tissues and organs.
- No treatment delay for patients who must also undergo chemotherapy as part of their breast cancer treatment.
- Cost savings to hospitals and breast cancer treatment centers.

In 1999, INTRABEAM® received both FDA clearance and CE Mark to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity or intraoperative radiotherapy treatments. The device is also approved for use in most countries around the world.

About the TARGIT-A trial

Since 1996, the international TARGIT research group has been researching a new method of delivering radiotherapy for breast cancer in which the treatment can be reduced to a single fraction at the time of surgery. In this way, the affected tissue in the tumor bed is irradiated from the inside out. The INTRABEAM® radiotherapy system from Carl Zeiss is used for this purpose. The study is testing whether the single dose can reduce the risk of recurrence of the cancer in the affected breast as effectively as the traditional, three to six week method. On a random basis, one half of the women taking part are offered conventional radiotherapy while the other half are offered to be treated intra-operatively. The results of the study will be presented for the first time during the 2010 annual meeting of the ASCO (American Society of Clinical Oncology) in Chicago from June 4-8. Please visit www.targit-research.org or www.targit.org.uk for more information.

About The INTRABEAM® System

INTRABEAM®, Carl Zeiss Meditec's ground breaking radiotherapy system, offers the least disruptive treatment method available to patients being treated for early stage breast cancer. The radiation dose of INTRABEAM® is administered to the tumor bed in the operating room. The system utilizes a miniature X-ray source, a highly flexible support stand and a full range of radiation applicator options. TARGIT has the advantage of precise radiation-dose delivery since the applicator is directly located into the tumor bed. Afterwards the applicator and miniature X-ray source are removed, the surgical site is closed, and the procedure is complete.^{2,3}

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US FDA-Cleared Indications for use:

The INTRABEAM® Spherical Applicators are indicated for use with the INTRABEAM® System to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity or intraoperative radiotherapy treatments. The INTRABEAM® Balloon Applicator together with the INTRABEAM® System is intended to deliver intracavitary or interstitial radiation to the surgical margins following lumpectomy of breast cancer. The safety and efficacy of the INTRABEAM® System as a replacement for whole breast irradiation in the treatment of breast cancer has not yet been established.

1. Vaidya JS, Baum M, Tobias JS et al. Protocol 99PRT/47, Targeted Intraoperative radiotherapy (Targit) for breast cancer. Lancet 1999; <http://www.thelancet.com/journals/lancet/misc/protocol/99PRT-47>
2. Vaidya JS, Baum M, Tobias JS et al. Targeted intra-operative radiotherapy (Targit): an innovative method of treatment for early breast cancer. Ann Oncol 2001; 12(8): 1075-80
3. Vaidya JS, Baum M, Tobias JS et al. The novel technique of delivering targeted intraoperative radiotherapy (Targit) for early breast cancer. Eur J Surg Oncol 2002; 28(4): 447-54

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Brief profile

Carl Zeiss Meditec AG (ISIN: DE 0005313704), which is listed on TecDAX of the German stock exchange, is one of the world's leading medical technology companies.

The company supplies innovative technologies and application-oriented solutions designed to help doctors improve the quality of life of their patients. It provides complete packages of solutions for the diagnosis and treatment of eye diseases - including implants and consumable materials.

The company creates innovative visualization solutions in the field of microsurgery. Carl Zeiss Meditec's medical technology portfolio is rounded off by promising future technologies such as intraoperative radiation therapy.

In the financial year 2008/2009 (30 September) the 2,100 employees generated revenue of approximately EUR 640 million. The head office of Carl Zeiss Meditec is in Jena, Germany. The company has subsidiaries in Germany and abroad; more than 50 percent of its employees are based in the USA, Japan, Spain and France.

35 percent of Carl Zeiss Meditec shares are in free float. The remaining 65 percent are held by Carl Zeiss AG, one of the world's leading groups engaged in the optical and opto-electronics industry—Carl Zeiss offers innovative solutions for the future-oriented markets of "Medical and Research Solutions," "Industrial Solutions" and "Lifestyle Products." The head office of Carl Zeiss AG is in Oberkochen, Germany. In financial year 2008/09 (balance sheet date 30 September) the group posted sales of around € 2.1 billion. The Carl Zeiss Group has approximately 13,000 employees, including more than 8,000 in Germany.

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