

Abstract e11577

Embargoed until May 18, 2011

Press Release

FOR IMMEDIATE RELEASE

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Study Evaluating SIR-Spheres[®] Microspheres in Patients with Metastatic Breast Cancer Presented at the 2011 American Society of Clinical Oncology Annual Meeting

CHICAGO (June 3, 2011) — [Sirtex](#), a leading developer and manufacturer of targeted, innovative liver cancer therapies, today announced the results of a five-year study evaluating the tolerability, efficacy and survival rates of Selective Internal Radiation Therapy (SIRT), also known as radioembolization, using SIR-Spheres[®] microspheres in patients with liver metastases from breast cancer that are refractory to chemotherapy. The study was led by Roberto Cianni, M.D., interventional radiologist at Santa Maria Goretti Hospital in Latina, Italy.

The study observed 49 patients undergoing treatment for breast cancer liver metastases. All eligible patients received radioembolization using SIR-Spheres (Yttrium-90 resin microspheres), and follow-up CT and PET exams were scheduled in eight and 12-week increments.

Utilizing Response Evaluation Criteria in Solid Tumors (RECIST) criteria, researchers noted complete response/partial response (CR/PR) in 24 patients (49%), stable disease (SD) in 17 patients (35%), and progressive disease (PD) in eight patients. Technical success rate and effectiveness, estimated at three months, were 98 percent and 80 percent, respectively. Side effects graded by Common Terminology Criteria on Adverse Events were represented by one grade 4 hepatic failure, one grade 2 gastritis and one grade 2 cholecystitis. The median survival and the progression-free survival calculated were 354 days (11.8 months) and 279 days (9.3 months), respectively.

“Our primary objective was to provide prolonged disease control for patients with liver-dominant metastatic breast cancer that was refractory to chemotherapy, since there are few effective treatment options available,” Dr. Cianni said. “The results of our study with SIR-Spheres are very encouraging, with 84 percent of the patients experiencing disease stabilization or tumor shrinkage and a prolonged progression free survival period. The treatment was also well-tolerated, which is an important consideration for patients.”

Researchers concluded that radioembolization using SIR-Spheres microspheres is effective and well-tolerated in patients with liver metastases from breast cancer. Response to therapy was supported by the decrease in tumor size and activity.

“Breast cancer remains a significant disease, affecting over 200,000 women in the U.S. and 450,000 in Europe,” said Nigel Lange, CEO, Sirtex Medical Europe GmbH. “Unfortunately, breast cancer spreads to the liver at some point in around one in four women and is a major cause of morbidity and mortality. The results of this study are very promising, particularly considering that the patients were heavily pre-treated and were no longer responding to chemotherapy.”

About Selective Internal Radiation Therapy using SIR-Spheres microspheres

Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a novel treatment for inoperable liver cancer that delivers high doses of radiation directly to the site of tumors. In a minimally-invasive treatment, millions of radioactive SIR-Spheres microspheres are infused via a catheter into the liver where they selectively target liver tumors with a dose of internal radiation up to 40 times higher than conventional radiotherapy, while sparing healthy tissue.

Clinical trials have confirmed that liver cancer patients treated with SIR-Spheres microspheres have response rates higher than with other forms of treatment, resulting in increased life expectancy, greater periods without tumor activity, and improved quality of life. SIRT has been found to shrink liver tumors more than chemotherapy alone.

Manufactured by Sirtex, SIR-Spheres microspheres are the only FDA-approved microsphere radiation therapy for the treatment of liver metastases. Over 18,000 treatments worldwide have been conducted to date using SIR-Spheres microspheres.

SIR-Spheres microspheres are approved for use in Australia, the European Union (CE Mark), New Zealand, Switzerland, Turkey and several other countries for the treatment of unresectable liver tumors. SIR-Spheres microspheres are also indicated in the U.S. for the treatment of non-resectable metastatic liver tumors from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using floxuridine. Information regarding other disease states or agents in combination with this device, that is presented in peer-reviewed literature or medical meetings may differ from the approved USA indications as per the labeling for the product.

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