Large U.S. Multi-Center Study Supports the Safety and Efficacy of Sirtex’s SIR-Spheres® microspheres in Treating Colorectal Liver Metastases

The Associated Press

SAN FRANCISCO--(BUSINESS WIRE)--Jan 24, 2013--The results of a large multi-center clinical study re-affirming the safety and efficacy of Selective Internal Radiation Therapy (SIRT) with SIR-Spheres ® microspheres in patients with metastatic colorectal cancer were presented today at the American Society of Clinical Oncology’s 2013 Gastrointestinal Cancers Symposium. 1,2 The data were presented by lead investigator Andrew S. Kennedy, M.D., F.A.C.R.O., Director, Radiation Oncology Research Sarah Cannon Research Institute, Nashville, TN.

SIR-Spheres microspheres are manufactured by Sirtex and are the only fully FDA PMA approved microsphere radiation therapy for the treatment of colorectal liver metastases. The microspheres are administered via the hepatic artery, either alone, or in conjunction with systemic chemotherapy.

“Our goal with these studies was to evaluate the overall survival, tumor response and safety of using microsphere therapy in patients who are no longer responding to chemotherapy,” said Dr. Kennedy. “Patients in the study had a history of heavy pre-treatment and presented challenges in finding an effective treatment option. These research findings should help to further define the role of SIRT in helping to shrink or control the tumors and prolong patient survival.” Multi-Institutional U.S. Study Overview This investigator initiated study was a retrospective analysis of the outcomes in 548 patients with metastatic colorectal cancer treated with SIR-Spheres microspheres from July 2002 to December 2011 at 11 U.S. institutions. 1 All patients had received prior chemotherapy, with more than 30% having also received prior liver surgery or ablation.

The authors reported median survivals of 13.0, 9.0 and 8.1 months, respectively, in patients who had received 1, 2 or 3+ prior lines of chemotherapy. There were no significant differences in the adverse event profiles between the three groups. Most patients (97.8%) spent less than 24 hours in the hospital with the most common Grade 3 side effects being abdominal pain (7%) and fatigue (6%). The authors concluded that SIRT with SIR-Spheres microspheres appears to have a favorable risk/benefit ratio in patients with metastatic colorectal cancer who have failed chemotherapy. These data show a clinically relevant survival benefit in patients not responding to chemotherapy, including those who have been heavily pre-treated.

Independent Imaging Study Confirms Efficacy with SIRT The second presentation from this study illustrated the response to SIRT therapy with SIR-Spheres microspheres from an imaging perspective. 2 The study presented the results of an

independent central review by a board-certified radiologist of 195 patients with metastatic colorectal cancer that were treated with SIR-Spheres microspheres and had measureable lesions at baseline and follow-up imaging. Tumor RECIST response at three months showed a Partial Response in 7.6% of patients, 47.3% experienced Stable Disease and 45.0% had Progressive Disease resulting in a Disease Control Rate of 55.0%. RECIST response at three months predicted median survival of 25.2 months in Partial Responders compared to 15.8 months in those with Stable Disease and 7.1 months with Progressive Disease.

Researchers noted that response to SIRT therapy at three months must be interpreted with caution due to the significant proportions of peri-tumoral edema and necrosis encountered. Both imaging findings may lead to either the underestimation of Partial Response/Stable Disease or the overestimation of Progressive Disease, respectively. Given these caveats, early hepatic radiological response to SIRT therapy appears to predict longer-term prognosis.

"These studies add to the growing body of scientific data further supporting the role of SIRT in treating metastatic colorectal cancer. In this specific patient population, the results compare favorably to many of recently approved chemotherapy and biologic agents, and provide another option to patients who may have stopped responding to systemic therapy," said Mike Mangano, president of Sirtex Medical Inc. "It is our intention to continue to study SIR Spheres microspheres in various patient populations, with the goal of adding this treatment to conventional chemotherapy even earlier in the treatment algorithm. The SIRFLOX study, which is expected to complete enrollment in the first quarter of 2013, will test this hypothesis with the hope that controlling liver tumors will allow patients to live longer and experience an improved quality of life. We look forward to those results."
About Selective Internal Radiation Therapy using SIR-Spheres microspheres
Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a proven technology for inoperable liver cancer that delivers 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 studies have confirmed that patients with metastatic colorectal cancer 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.

SIR-Spheres microspheres are approved for use in Australia, the United States of America (FDA PMA approval), the European Union (CE Mark) and Argentina (ANMAT). Additionally, SIR-Spheres microspheres are supplied in countries such as Hong Kong, Malaysia, Singapore, Thailand, Taiwan, India, Israel, and Turkey. Available at more than 500 treatment centers, over 25,000 doses of SIR-Spheres microspheres have been supplied worldwide.

For more information, visit www.sirtex.com.

SIR-Spheres ® is a registered trademark of Sirtex SIR-Spheres Pty Ltd.

References: 1. Kennedy AS, Ball D, Steven J. Cohen SJ et al. Safety and efficacy of resin 90 Y-microspheres in 548 patients with colorectal liver metastases progressing on systemic chemotherapy. ASCO Gastrointestinal Cancers Symposium 2013; Abs. 264.

2. Kennedy AS, Ball D, Steven J. Cohen SJ et al. Hepatic imaging response to 90 Y-microsphere therapy administered for tumor progression during systemic chemotherapy in patients with colorectal liver metastases. ASCO Gastrointestinal Cancers Symposium 2013; Abs. 270.

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