

Press Release

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Study Establishes Safety and Clinical Benefit of SIR-Spheres[®] microspheres in Treating Metastatic Liver Tumors in Patients who Failed Systemic Chemotherapy

SAN FRANCISCO (March 27, 2012) — SIR-Spheres[®] microspheres are safe and provide clinical benefit for patients with colon cancer liver metastases who have previously received liver-directed and systemic chemotherapy, according to the results of a prospective clinical study announced today at the Society of Interventional Radiology's 37th Annual Scientific Meeting. The data were presented by the interventional investigator Constantinos T. Sofocleous, M.D., in collaboration with Nancy Kemeny, M.D., GI Medical Oncologist from Memorial Sloan-Kettering Cancer Center in New York. SIR-Spheres microspheres are manufactured by [Sirtex](#), a leading developer of targeted, innovative liver cancer therapies.

The prospective single-center study assessed the safety, dose-limiting toxicities and the maximum tolerated dose of SIR-Spheres microspheres in a population whose cancer had progressed despite hepatic arterial and systemic chemotherapy treatments. Over the two year period, from September 2009-2011, 19 patients received SIR-Spheres microspheres in three escalating dose levels. The first group received 70%, the second group received 85%, and the third group received 100% of their specific calculated dose. Common side effects from the SIR-Spheres microspheres were mild-to-moderate (grade 1 or 2) fatigue and mild (grade 1) fever, which were self-limiting and transient. One patient experienced grade 3 nausea and pain, and two patients had elevated bilirubin levels attributed to progressive disease.

Evaluations 4-8 weeks post-treatment showed 12 patients (65%) with stable disease, while five (29.4%) saw disease progression. Median progression-free and overall survival were 6 (95% CI: 3.2-9.7) and 16 (95% CI: 5.8-17.6) months, respectively. All patients received further chemotherapy, 9 further HAI therapy, with 4 having a decrease in CEA.

Based on these findings, researchers concluded it is safe to administer the entire dose of SIR-Spheres microspheres in patients with colon cancer metastases who progressed despite prior pump and systemic chemotherapy.

“This study helps to confirm that we need to identify more effective treatment options for patients with colorectal liver metastases,” said Dr. Sofocleous. “These results have met our expectations regarding safety of SIRT in heavily pre-treated patients with good liver functions.”

For more information visit www.Sirtex.com or find the latest updates on the SIR-Spheres microspheres Facebook page (www.Facebook.com/SIRSpheresmicrospheres).

About Selective Internal Radiation Therapy (SIRT) using SIR-Spheres microspheres

Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a novel 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 trials 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 approval), and the European Union (CE Mark) and additionally supplied in countries such as Hong Kong, Malaysia, Singapore, Thailand, Taiwan, India, Israel and Turkey. Available at more than 400 treatment centers, over 20,000 doses of SIR-Spheres microspheres have been administered worldwide.

For more information, visit www.sirtex.com.

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