



Press Release

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Sirtex Supports the First Pilot Study Evaluating SIR-Spheres® Microspheres in Combination with Bevacizumab and Chemotherapy as a First Line Treatment for Metastatic Colorectal Cancer

Prospective Multi-Center Trial to evaluate safety and tolerability of combination therapies in patients with advanced liver disease

LAKE FOREST, Ill. (February 8, 2007) – Sirtex, a leading developer of targeted and innovative cancer therapies, is pleased to announce its support of a clinical study evaluating the safety of SIR-Spheres® microspheres when administered with bevacizumab, an anti-angiogenic agent, and chemotherapy as a first-line treatment for patients with colorectal cancer that has metastasized to the liver. The “FAST” trial will evaluate the concurrent administration of either FOLFOX6 or FOLFIRI and bevacizumab with Selective Internal Radiation Therapy (SIRT) using SIR-Spheres microspheres. Andrew Kennedy, M.D., co-medical director of Wake Radiology Oncology in Cary, N.C., will serve as principal investigator for the trial.

SIR-Spheres microspheres are currently approved by the FDA for the treatment of unresectable metastatic liver tumors from primary colorectal cancer together with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).¹

“The evaluation of SIR-Spheres microspheres with bevacizumab in combination with newer chemotherapy agents marks a major step in the treatment of advanced liver tumors,” says Kennedy. “This trial is the first to incorporate a central review of radiation dosimetry which means we will be able to carefully determine the amount of radiation delivered to the liver for each participant. Also, since bevacizumab is an anti-angiogenic and inhibits blood flow to tumors, this trial will analyze the vascular effects of bevacizumab with chemotherapy. All of these elements make the trial pivotal as we work to advance the treatment of colorectal liver metastases.”

The study has received an IRB approval and participants are required to sign a patient consent form prior to treatment. Eligible participants must be 18 years or older with histological proof of metastatic colorectal cancer to the liver, have an ECOG score of two or less and have a life expectancy of at least three months.

Participants will receive chemotherapy with bevacizumab and SIR-Spheres microspheres on an outpatient basis, and be monitored for 90 days. Along with safety endpoints, the study will help provide a better understanding of the potential advantages and limiting toxicity of combined chemotherapy and liver brachytherapy. The results of the trial will be used to develop and refine the treatment plan for an intended larger clinical study.

The trial is being conducted in five sites across the nation including Wake Radiology Oncology in Cary, N.C., Skyridge Medical Center in Lone Tree, Colo., St. Vincent's Hospital in Portland, Ore., Brown University, Rhode Island Medical Center in Providence, R.I. and William Beaumont, Royal Oak, Mich.

¹ Sirtex Medical Inc.'s SIR-Spheres® microspheres are indicated for the treatment of non-resectable metastatic colorectal cancer in combination with intra-arterial FUDR chemotherapy. Information regarding other disease states or agents in combination with this device that is presented in peer reviewed literature is different from the approved USA labeling for SIR-Spheres.

About Sirtex

SIR-Spheres microspheres were developed in the 1980s in Australia and gained FDA approval in March 2002. Sirtex has obtained regulatory approval to market SIR-Spheres microspheres in the United States, European Union, Israel and Australia. The product is marketed in New Zealand, Hong Kong, Malaysia, Singapore and Thailand. For more information, visit www.sirtex.com.

About SIR-Spheres microspheres

Sirtex's SIR-Spheres microspheres are radioactive polymer spheres that emit beta radiation. Physicians insert a catheter through the groin into the hepatic artery and deliver millions of SIR-Spheres microspheres directly to the tumor site. The SIR-Spheres microspheres target the liver tumors, sparing healthy liver tissue. Approximately 55 physicians in the United States use Sirtex's SIR-Spheres microspheres in more than 60 medical centers. The minimally invasive procedure is performed on an out-patient basis with usually only minor side effects.