

Abstract e14612  
Embargoed until May 18, 2011

## Press Release

FOR IMMEDIATE RELEASE

Contact: Kassidie Blackstock

Phone: 919-457-0749

Email: [Kassidie.Blackstock@fleishman.com](mailto:Kassidie.Blackstock@fleishman.com)

### **Fox Chase Cancer Center Study Evaluating the Safety of Concurrent Chemotherapy and Selective Internal Radiation Therapy using SIR-Spheres<sup>®</sup> Microspheres Released at 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 Phase I study evaluating the safety and efficacy of concurrent treatment using capecitabine in combination with Selective Internal Radiation Therapy (SIRT), also known as radioembolization, using SIR-Spheres<sup>®</sup> microspheres to treat liver tumors. The data were released at the 2011 Annual Meeting of the American Society of Clinical Oncology by lead investigator Steven J. Cohen, M.D., Chief of Gastrointestinal Medical Oncology at Fox Chase Cancer Center and Associate Medical Director for Fox Chase Cancer Center Partners.

SIRT with SIR-Spheres (Yttrium-90 resin microspheres) is an emerging treatment for liver tumors, both alone and in combination with chemotherapy. Capecitabine is a frequently used chemotherapeutic agent for the treatment of breast cancer and colorectal cancer. Both capecitabine and SIR-Spheres microspheres are approved by the FDA, although concurrent use of capecitabine with SIRT has been contraindicated due to concerns for liver toxicity.

“We initiated this study to determine if capecitabine could be given safely in conjunction with SIR-Spheres,” Dr. Cohen said. “At this point in the trial, and as we continue to gather data, we feel comfortable that these two treatments can be administered concurrently because safety signals, above those that would be expected with standard chemotherapy and SIR-Spheres, have not been observed when capecitabine has been used at clinically relevant concentrations. Although response is not the primary endpoint, we are encouraged with the clinical activity to date.”

#### **Single Center Study**

During the study, 21 patients with unresectable metastatic or primary liver tumors who typically had failed other therapies were treated with escalating doses of capecitabine; SIR-Spheres microspheres were introduced on day two of capecitabine treatment. The safety of each dose was evaluated prior to continuing the study and administering an escalated dose of capecitabine.

Inclusion criteria included liver-only or liver-dominant disease, and any prior treatments were not an excluding factor. Patients had a median age of 61 years, consisted of 13 males and eight females, had failed a median of two prior therapies and had the following diagnoses: 16 colorectal cancer, one neuroendocrine cancer, one biliary cancer, one hepatocellular cancer, one small bowel cancer and one unknown. Patients were placed as follows: Group 1 (8 patients) was treated twice-daily with 375mg/m<sup>2</sup>; Group 2 (4 patients) was treated twice-daily with 600 mg/m<sup>2</sup>; Group 3 (6 patients) was treated twice-daily with 750 mg/m<sup>2</sup>; and, Group 4 (3 patients) was treated twice-daily with 900 mg/m<sup>2</sup>.

## **Results**

Of Group 1, one patient with biliary cancer had grade 3 hyperbilirubinemia possibly related to toxicity, and one patient with colorectal cancer had grade 4 hyperbilirubinemia related to disease. No other dose limiting toxicities (DLTs) were observed in the remaining six patients. No patients in Group 2 had any DLTs. One patient in Group 3 had a partial antral perforation possibly related to toxicity; the group was expanded and no other DLTs were observed. No DLTs were observed in patients receiving 900 mg/m<sup>2</sup> twice-daily in Group 4.

Common grade 1 or 2 non-hematological toxicities included transaminitis/alkaline phosphatase elevation (9), nausea (8), pain (7), fatigue (5) and hand/foot syndrome (5).

Of the 21 patients involved in the study, four (19%) exhibited a partial response to the concurrent therapy; 16 (76%) reported stable disease; and one showed progressive disease, demonstrating a disease control rate of 95%.

Based on the study results, researchers concluded capecitabine can be safely administered with SIR-Spheres microspheres at doses typically utilized with combination chemotherapy (up to 900 mg/m<sup>2</sup> twice-daily). Further evaluation in colorectal cancer patients is planned.

“Each year, over 70,000 people in the U.S. and 225,000 in Europe are diagnosed with colorectal cancer that has spread to the liver,” said Mike Mangano, President, Sirtex Medical Inc. “Surgery is rarely an option, and other treatment options for these patients are limited, particularly once patients have failed chemotherapy. Sirtex is committed to the safe and appropriate use of SIR-Spheres microspheres, and these preliminary results from Fox Chase Cancer Center further support the safety of SIR-Spheres microspheres when used in combination with standard chemotherapy regimens.”

## **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 colorectal liver metastases. Over 18,000 treatments worldwide have been conducted using SIR-Spheres microspheres.

SIR-Spheres microspheres are indicated in the U.S. for the treatment of non-resectable metastatic liver tumors from primary colorectal cancer in combination with adjuvant intra-hepatic artery chemotherapy using floxuridine. SIR-Spheres microspheres are also 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. 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 U.S. FDA indications as per the labeling for the product.

SIR-Spheres<sup>®</sup> is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd

#### **About Fox Chase Cancer Center**

[Fox Chase Cancer Center](http://www.foxchase.org) is one of the leading cancer research and treatment centers in the United States. Founded in 1904 in Philadelphia as one of the nation's first cancer hospitals, Fox Chase was among the first institutions to be designated a National Cancer Institute Comprehensive Cancer Center in 1974. Fox Chase researchers have won the highest awards in their fields, including two Nobel Prizes. Fox Chase physicians are routinely recognized in national rankings, and the Center's nursing program has received the Magnet status for excellence three consecutive years. Fox Chase conducts a broad array of nationally competitive basic, translational, and clinical research, with special programs in cancer prevention, detection, survivorship, and community outreach. For more information, visit Fox Chase's web site [www.foxchase.org](http://www.foxchase.org) or call 1-888-FOX CHASE or (1-888-369-2427).

###