Sirtex Completes Patient Recruitment for SIRFLOX Study Evaluating SIR-Spheres® Microspheres as First-Line Treatment for Colorectal Liver Metastases

World’s Largest Interventional Oncology Study with More Than 500 Patients Enrolled

WOBURN, Mass. (April 13, 2013) — Sirtex Medical Limited (ASX:SRX), a leading manufacturer of targeted, innovative liver cancer therapies, announced yesterday the completion of patient recruitment into the group’s landmark SIRFLOX randomized controlled trial of SIR-Spheres® microspheres for patients with metastatic colorectal cancer. The SIRFLOX study is the world’s largest randomized controlled trial in interventional oncology with more than 500 patients enrolled.

The SIRFLOX study aims to evaluate whether a first-line treatment strategy of standard-of-care chemotherapy plus SIR-Spheres microspheres is more effective in delaying cancer progression than chemotherapy alone, in patients with inoperable liver metastases from primary colorectal cancer. Completing recruitment into the study required the participation of more than 100 leading hospitals globally over a six year period.

“Sirtex is committed to delivering large, randomized controlled trials to confirm the results from the numerous, smaller, peer-reviewed studies demonstrating the effectiveness of SIR-Spheres microspheres,” said Mike Mangano, President of Sirtex Medical Inc. “We anticipate that the data from the SIRFLOX study will provide sufficient proof to the oncology community that combining chemotherapy and internal radiation therapy earlier in the treatment algorithm will benefit patients.”

Twenty-one U.S. sites have enrolled patients into the SIRFLOX study. Primary results from the study are expected to be available in late 2014.

“Our clinical experience has shown SIR-Spheres microspheres to be an effective treatment option for patients with metastatic colorectal cancer,” said Fred Moeslein, SIRFLOX investigator and Interim Director, Division of Vascular and Interventional Radiology at University of Maryland School of Medicine. “We are excited to be the top enrolling U.S. site in this landmark study and look forward to seeing the results which we believe will help further guide the oncology community in best practice treatment for liver tumors from metastatic colorectal disease.”

For more information on the SIRFLOX study, visit www.sirflox.com.
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 600 treatment centers, over 34,000 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.