Sirtex Medical Inc. Expands Business into Brazil, Experiences Record Growth

First SIR-Spheres® microspheres treatment at Hospital Sirio-Libanes in Sao Paulo, Brazil

WOBURN, Mass. (September 8, 2014) — Sirtex Medical Inc., a subsidiary of Sirtex Medical Limited (ASX:SRX), a leading manufacturer of targeted, liver cancer therapies, announced today the expansion of its business in Latin America. Sirtex’s SIR-Spheres® microspheres are now available to treat inoperable liver tumors in Brazil. The first SIR-Spheres microspheres treatments took place the first week of September at Hospital Sirio-Libanes in Sao Paulo. Sirtex received product approval from the Agência Nacional de Vigilância Sanitária (ANVISA) for SIR-Spheres microspheres early in 2014.

The announcement comes at a time when the America’s region is experiencing record growth, having recently announced that dose sales of SIR-Spheres microspheres grew a solid 22.5 percent, with more than 5,836 doses being supplied for the fiscal year ending June 30, 2014.

Brazil represents the largest economy and medical device market in Latin America. Many thousands of Brazilians will develop liver tumors. For example, at least 60 percent of the 14,200 Brazilians diagnosed with colorectal cancer every year will see their cancer spread to the liver, with many dying of the disease due to lack of treatment options.¹

“Over the last several years we have been meeting with healthcare professionals and regulatory authorities from Brazil to identify the market demands and understand the patient needs,” commented Mike Mangano, president of Sirtex Medical. “The availability of SIR-Spheres microspheres, at such a world-renowned institution as Sirio-Libanes in Sao Paulo, provides greater hope to patients with liver tumors.”

“I am delighted to announce that we have performed the first SIR-Spheres microspheres treatments in Brazil. I am honored to represent the entire multidisciplinary team at Sirio-Libanes and the University of Sao Paulo, as well as our colleagues at Sirtex who have worked so hard to make this therapy possible,” said Dr. Francisco Carnevale, chief of the interventional radiology section, University of Sao Paulo. “In the past, we were able to offer patients limited targeted liver treatments for cancer. The addition of SIR-Spheres microspheres is important as we evolve our patient treatment options. The peer-reviewed literature shows SIR-Spheres microspheres extend patient survival while maintaining a good quality of life.”
Dr. Frederico Costa, medical oncologist, Sirio-Libanes, added, “SIR-Spheres microspheres are another powerful weapon against liver tumors when integrated as part of a multidisciplinary treatment plan. Having this treatment available at Sirio-Libanes allows us to complement our systemic chemotherapy treatments and optimize patient outcomes.”

Commenting on the financial results, Mangano said, “The consistent and encouraging growth in the Americas region, with the first patients now being treated in Brazil, reflects the increased acceptance of SIR-Spheres microspheres as a key option for appropriate patients. We continue to invest in our Americas organization, and will also triple our manufacturing capacity at our Wilmington, Massachusetts facility by the end of this year. We expect continued momentum coupled with the highly anticipated results of the SIRFLOX study in the first quarter of 2015 which we believe will help fuel our growth.”

Globally, revenue was $129.4 million Australian dollars with worldwide sales of 8,561 doses, up 17.3 percent in fiscal year 2014, with Asia Pacific reporting growth of 12.4 percent and Europe, Middle East and Africa increasing 5.6 percent.

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

About the SIRFLOX Study

The SIRFLOX study is an international, multicenter, randomized controlled study that enrolled over 500 patients with metastatic colorectal cancer whose disease was inoperable and had spread to either the liver alone or the liver plus a limited number of sites outside the liver. The study was conducted in more than 100 centers in the US, Australia, Europe, Israel, and New Zealand. SIRFLOX is the first, large randomized controlled study that has examined the use of selective internal radiation therapy in this patient group.

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.
In the U.S., SIR-Spheres microspheres are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Flouxuridine). SIR-Spheres microspheres are approved for use in Argentina, Brazil, Australia, the European Union and several countries in Asia for the treatment of unresectable liver tumors.

Available at more than 400 treatment centers in the U.S., over 45,000 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.

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