



ASX Announcement  
27 July 2007

**Sirtex Announces First Randomised Trial Evaluating SIR-Spheres® Microspheres for the Treatment of Inoperable Primary Liver Cancer**

Australian-based medical device company Sirtex Medical Limited (SRX) has announced the activation in Europe of the first randomised clinical trial to evaluate selective internal radiation therapy (SIRT) using the company's SIR-Spheres microspheres against trans-catheter chemo-embolisation (TACE) to treat patients with inoperable primary liver cancer (hepatocellular carcinoma).

The pilot clinical trial, sponsored by Sirtex, will evaluate the health-related quality of life, pharmaco-economic parameters, safety and efficacy of SIR-Spheres microspheres compared to treatment with TACE, which involves delivering chemotherapy drugs directly to the liver.

The co-principal investigators for the trial are Dr. Bruno Sangro, Hepatologist from the Liver Unit, University Clinic of Navarra, Pamplona, Spain and Prof. Dr. Frank Kolligs, Hepatologist from the Ludwig Maximilians University of Munich, Germany. These two institutions each have leading liver cancer programs, and are the most experienced European centres in the clinical application – and research use – of yttrium-90 microspheres (SIR-Spheres).

Primary liver cancer is the fifth most common cancer in the world, with more than 1.25 million cases occurring annually. It is a leading cause of cancer-related mortality in both men and women worldwide, with an increasing incidence rate and a predominance in developing countries.

Liver transplantation and surgery are the most effective treatment options; however, approximately 80 percent of patients with primary liver tumours cannot be treated via liver transplantation or surgery.

“We are pleased to announce the activation of this clinical study for primary liver cancer, which will use a randomised, prospective, open design,” said Sirtex CEO Mr. Gilman Wong.

“SIR-Spheres microspheres have been used extensively in Europe, Asia and Australia/New Zealand for the treatment of primary liver cancer. This study aims to further evaluate the safety and effectiveness of Selective Internal Radiation Therapy using SIR-Spheres microspheres in patients with liver cancer.”

---

® SIR-Spheres is a registered trademark of Sirtex SIR-Spheres Pty Ltd

A total of 28 participants will be recruited to the pilot trial. Eligible patients must be 18 years or older and have confirmed primary hepatocellular carcinoma, confined to the liver. Patients will receive one or two treatments with SIR-Spheres microspheres, or TACE treatment repeated at 6-weekly intervals. There is a planned 6 months of accrual and 12 months of follow-up beyond the last patient enrolled in the study.

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

Selective Internal Radiation Therapy (SIRT) is a novel treatment for inoperable liver cancer that delivers high doses of radiation directly to the site of tumours. In a minimally invasive treatment, millions of radioactive SIR-Spheres microspheres are infused via a catheter into the liver where they selectively target liver tumours 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 liver metastases from primary colon or rectal cancer treated with SIR-Spheres microspheres have higher response rates than those treated with standard chemotherapy alone, resulting in increased life expectancy, greater shrinkage of liver tumours, longer periods without tumour activity, and improved quality of life.

SIRT using SIR-Spheres microspheres is approved for use in Australia, New Zealand, the United States of America (FDA approval), European Union (CE Mark) and Israel and is also supplied in Hong Kong, Malaysia, Singapore, Thailand and India. SIRT is available in approximately 160 treatment centres around the world, and more than 6500 patients have been treated to date.

### **About Liver Cancer**

Liver cancer is the biggest cancer-related killer of adults in the world. Each year, more than 1.25 million new cases of primary liver cancer develop worldwide and at least 200,000 new cases of secondary liver cancer develop from primary bowel cancer alone. It is estimated that secondary liver cancer is the ultimate cause of death for one in three cancer sufferers. Liver tumours are inoperable in approximately 80 per cent of cases, and are typically incurable with chemotherapy.

#####

For more information, visit our website at [www.sirtex.com](http://www.sirtex.com)

Contact: Gilman Wong, CEO, +61-2-9936-1400