Sirtex Medical receives US FDA approval to proceed with FAST clinical trial: Update on Clinical Trial Evaluating SIR-Spheres Microspheres with Bevacizumab and Chemotherapy as a First-Line Treatment for Unresectable Metastatic Colorectal Cancer

Biotechnology and medical device company Sirtex Medical Limited (SRX) is pleased to announce that it has received final approval from the United States Food and Drug Administration (FDA) to conduct the FAST clinical trial, the first clinical trial to evaluate the safety of concurrent administration of selective internal radiation therapy (SIRT) using SIR-Spheres microspheres; FOLFOX6 chemotherapy; and bevacizumab, an anti-angiogenic agent as first-line treatment of patients with colorectal cancer that has metastasized to the liver.

Sirtex Medical, the sponsor of the FAST study has received an Investigational Device Exemption (IDE) from the FDA, which is a necessary prerequisite for conducting such a clinical trial when being conducted by an industry sponsor.

The FAST clinical trial will be led by Dennis Carter, M.D. Radiation Oncologist from Rocky Mountain Cancer Center and Charlie Nutting, D.O. Interventional Radiologist at Skye Ridge Medical Center, both in Denver, Colorado, USA. The FAST study is being conducted at four US institutions and is scheduled to open for patient recruitment during Q2 2008.

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

Selective internal radiation therapy 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 cancer treated with SIR-Spheres microspheres have response rates higher than with other forms of treatment, resulting in increased life expectancy, greater periods without tumour activity, and improved quality of life. SIRT has been found to shrink liver tumours more than chemotherapy alone.

SIRT using SIR-Spheres microspheres is approved for use in Australia, New Zealand, the United States of America (FDA approval), European Union (CE Mark), Hong Kong, Malaysia, Singapore, Thailand, Israel, and India. SIRT is available in 140 treatment centres around the world, and more than 7,500 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 500,000 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 typically inoperable in 90 per cent of cases, and are usually incurable with chemotherapy.

For more information, visit our website at www.sirtex.com

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