



MEDIA RELEASE

Independent Multicentre Study Confirms Substantial Survival Benefit from SIR-Spheres Microspheres in Patients with Colorectal Cancer Liver Metastases who have Failed Chemotherapy

Sydney – June 3, 2008 – SIR-Spheres microspheres provides a substantial clinical benefit for patients with colorectal cancer that has spread to the liver and who have also failed available chemotherapy options, according to the results of an independent, prospective, multicentre phase II study conducted by the Italian Society of Locoregional Therapies In Oncology (SITILLO).¹ The results of the study were reported today at the American Society of Clinical Oncology (ASCO) conference held in Chicago, 30 May to 3 June 2008.¹

The SITILLO study is the first prospective clinical trial of SIR-Spheres microspheres in the salvage therapy of patients with colorectal cancer liver metastases who have been heavily pre-treated with chemotherapy. The results reveal a median overall survival of 13 months, with an overall response rate of 24% and stable disease reported in a further 24% of patients. The tumours shrank sufficiently to permit the surgeons to plan potentially curative surgery in two patients. Patients that responded to SIR-Spheres microspheres had a significantly longer median survival compared to non-responders (16 months versus 8 months; $P = 0.0006$), with 40% of the responders remaining alive at two years compared to none of the non-responders. Treatment with SIR-Spheres microspheres was well tolerated, with side effects in the first 30-days post-treatment consisting mostly of fever in 16% of patients in the first 48 hours and 22% after 48 hours.

“The results of the SITILLO study confirm the results of retrospective studies on SIR-Spheres microspheres in routine clinical practice, and also compare favourably with the results of chemotherapy alone,” said Gilman Wong, Chief Executive Officer of Sirtex Medical Limited “These results clearly demonstrate that SIR-Spheres microspheres should, at a minimum, be used for patients with colorectal cancer liver metastases who have failed chemotherapy. However, the investigators also noted the potential for SIR-Spheres microspheres to be combined with chemotherapy in order to further increase the effectiveness of treatment at earlier stages of the disease.”

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

Selective Internal Radiation Therapy is a novel treatment for inoperable liver tumours that delivers high doses of radiation directly to the site of the 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 radiation up to 40 times higher than can be safely delivered by convention radiotherapy, whilst at the same time sparing healthy tissue.

Clinical trials have confirmed that patients with liver cancer treated with SIR-Spheres microspheres have higher response rates and longer time to progression of the disease as well as survival compared with other forms of treatment. This leads to an increased life expectancy, greater periods with tumour activity, and improved quality of life compared to chemotherapy alone.

SIRTeX

SIRT using SIR-Spheres microspheres is used in Australia, New Zealand, the United States (FDA approval), European Union (CE Mark), Hong Kong, Israel, Malaysia, Singapore, Taiwan, Thailand and Turkey and over 7,500 patients have been treated to date.

About Liver Cancer

Liver cancer is the biggest killer of adults in the world. Each year, more than 500,000 cases of primary liver cancer develop world-wide, and at least 200,000 cases of secondary liver cancer develop from primary bowel cancer alone. It is estimated that secondary liver cancer is the ultimate cause of death in one in three cancer sufferers. Liver tumours are typically inoperable in 90 per cent of cases, and are usually incurable with chemotherapy.

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References

1. Cosimelli M, Mancini R, Carpanese L *et al.* Clinical safety and efficacy of ⁹⁰yttrium resin microspheres alone in unresectable, heavily pre-treated colorectal liver metastases: results of a phase II trial. ASCO Annual Meeting Proceedings *Journal of Clinical Oncology* 2008; **26** (May 20 Supplement): Abs. 4078.