



ASX Announcement

NEW CLINICAL TRIALS

Sydney Australia, 27 September 2006

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Sirtex Medical Limited is pleased to announce it has activated two further clinical trials to take place in Australia. These trials were suggested in a previous ASX announcement on 8 September 2005, written approval has recently been granted at the first hospital to proceed with patient recruitment for these two clinical trials.

Clinical Trial 1: Randomised Trial of SIR-Spheres plus chemotherapy

Colorectal cancer is one of the commonest cancers in the western world and in approximately 40% of patients it spreads to the liver and is incurable. Although chemotherapy is by far the commonest way to treat these patients, the increased survival benefit from chemotherapy is only of the order of twelve months.

There are now several publications showing that combining chemotherapy together with SIR-Spheres results in a high response rate. There is also published data showing that combining an older chemotherapy regimen with SIR-Spheres is better than using that chemotherapy alone in this same patient population.

As new and better chemotherapy regimens have evolved in recent years, it is imperative that Sirtex evaluate if the addition of SIR-Spheres will improve the outcome over using the best available chemotherapy alone. To date SIR-Spheres are largely used to treat patients who have already failed chemotherapy and for whom there are no other treatment options.

The international medical community is demanding a large randomised trial to address this question so that physicians can quantify the benefit that adding SIR-Spheres confers on their patients. As Sirtex has already demonstrated that this combination is well tolerated and results in a high response rate (see: ASX Announcement of 18 May 2005), this new trial will quantify the size of any benefit in a randomised trial that will largely satisfy that demand.

Therefore, Sirtex is sponsoring a randomised trial in patients with primary colorectal cancer (bowel cancer) that has spread to the liver, but who have not yet received chemotherapy. The trial is designed to recruit 258 patients from approximately 25 major hospitals throughout Australia, New Zealand, the USA and the European Union to evaluate the benefit of adding a single treatment with SIR-Spheres to state-of-the-art chemotherapy.

If this trial can clearly demonstrate an improvement over the best available chemotherapy, it would be a major finding and will position the use of SIR-Spheres together with chemotherapy as a preferred first treatment option for this large patient population.

Clinical Trial 2: Trial of SIR-Spheres in Metastatic Pancreas Cancer

Although pancreas cancer is one of the less common cancers, it is almost universally fatal with approximately half the deaths directly attributable to spread to the liver. For instance there are approximately 2,000 new cases of pancreas cancer in Australia each year and more than 98% will succumb to their disease. Chemotherapy is frequently used to treat these patients, but improves median survival by only a few weeks.

Sirtex Medical Limited has anecdotal evidence that in many patients, treatment with SIR-Spheres will cause regression of the liver tumours that have spread from the pancreas. If Sirtex can demonstrate in a randomised clinical trial that there is a significant survival benefit by using SIR-Spheres in these patients, it would be a great importance. Any increase in survival over what chemotherapy can provide would immediately position SIR-Spheres as a treatment of choice.

Therefore, a two stage clinical trial process has been started, with the first stage now open for patient entry. This first stage will recruit ten patients with pancreas cancer that has spread to the liver from three cancer centres in Australia. Treatment will involve a combination of SIR-Spheres plus chemotherapy. This trial is expected to produce outcome results within a year.

If the treatment is well tolerated and shows patients benefiting, a much larger randomised trial will immediately follow with recruitment from USA and possibly Europe as well.

As reported to shareholders at the last Annual General Meeting, Sirtex Medical Limited has a strategy to undertake many clinical trials involving SIR-Spheres over the next several years and will announce each of these trials as they are activated.

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

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