



ASX / MEDIA RELEASE

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Australian mCRC Patient Registry Analysis of SIR-Spheres Microspheres Utilisation Presented at the AGITG Annual Meeting

Sydney, Australia; 3rd September 2015 – Sirtex Medical Limited (ASX:SRX) announced today that a presentation entitled “Current utilisation of Selective Internal Radiation Therapy (SIRT) in metastatic colorectal cancer (mCRC) in Australia” was highlighted at the 17th Annual Scientific Meeting of the Australasian Gastro-Intestinal Trials Group (AGITG) in Sydney.

The presentation, which was independent of Sirtex, reported outcomes of patients treated with SIR-Spheres[®] Y-90 resin microspheres in first-line mCRC. These data were extracted from a large, prospective multi-site Australian mCRC patient registry¹. This registry, which is supported by a major global pharmaceutical company, consists of consecutive patients enrolled from January 2009 onwards.

The aim of the analysis was to compare the characteristics and outcomes for patients selected for SIRT plus chemotherapy versus a similar group of patients who received chemotherapy only. A total of 30 patients with liver-only disease who were non-resectable and therefore treated with palliative intent, received SIRT plus first-line chemotherapy, whereas 188 patients received chemotherapy only.

It was reported that SIRT plus chemotherapy treated patients versus chemotherapy only treated patients had a median overall Progression-Free Survival (PFS) of 10.6 months versus 9.9 months, with a hazard ratio (HR) = 0.87, which was not statistically significant ($p = 0.18$). However, it was also reported that SIRT plus chemotherapy treated patients versus chemotherapy only treated patients had a median Overall Survival (OS) of 24.3 months versus 19.3 months, with a HR = 0.73, which was statistically significant ($p = 0.038$).

The authors concluded that “SIRT is rarely used in the first-line treatment of mCRC in routine practice. A multivariate analysis will be performed to better understand the observed survival data. However, the available data suggests that OS gains can be seen in the absence of differences in PFS.”

Dr David N. Cade, Chief Medical Officer of Sirtex Medical commented “The recent presentation of SIRFLOX clinical data showed a clinically significant 7.9 month delay in tumour progression in the liver for patients treated with SIR-Spheres microspheres, even though there was no difference in overall PFS at any site in the body. The mCRC registry findings presented at AGITG are consistent with our view that delaying tumour progression in the liver is a worthwhile treatment objective, if that could translate to an overall survival benefit in patients treated with SIR-Spheres microspheres under a prospective clinical study design. However, it is important to recognise there are limitations to the independent analysis undertaken on the mCRC registry for SIRT, which relates to the modest sample size and non-randomised nature of the data presented.”

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Dr Cade further commented “The survival benefit observed in first-line mCRC patients treated with SIR-Spheres microspheres plus chemotherapy on the Australian mCRC patient registry underlines the importance of our continuing clinical studies program, which will examine OS data from the combination of our three large, multi-centre, randomised controlled studies SIRFLOX, FOXFIRE and FOXFIRE Global representing over 1,100 patients globally. We expect these data to be available in 2017.”

About AGITG

The AGITG Scientific Meetings are held annually to provide gastro-intestinal (GI) cancer researchers and specialists with the opportunity to present their recent research into GI cancers and to discuss the current challenges and potential solutions across the field. AGITG research is multi-disciplinary and the membership represents all the relevant disciplines: medical oncology, surgery, radiation oncology, biology, pathology, statistics and study coordination. The AGITG Annual Scientific Meetings attract Australasia’s leaders in the field of GI cancer research and treatment.

About SIR-Spheres® Y-90 Resin Microspheres

SIR-Spheres Y-90 resin microspheres are a medical device used in interventional oncology to deliver Selective Internal Radiation Therapy or SIRT (also known as radioembolisation), a proven technology for inoperable liver tumours that delivers substantial, targeted doses of radiation directly to the cancer. Key SIR-Spheres Y-90 resin microspheres regulatory approvals include Pre-Market Approval (PMA) from the US FDA, European Union (CE Mark) approval and Australian TGA approval.

About Sirtex Medical

Sirtex Medical Limited (ASX:SRX) is an Australian-based global healthcare business working to improve outcomes in people with cancer. Our current lead product is a targeted radiation therapy for liver cancer called SIR-Spheres® Y-90 resin microspheres. Approximately 55,000 doses have been supplied to treat patients with liver cancer at more than 900 medical centres in over 40 countries. For more information please visit www.sirtex.com.

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

¹ Data sourced from the Treatment of Recurrent and Advanced Colorectal Cancer (TRACC) registry comprising 1,694 patients with mCRC. The TRACC database is supported by Roche Products Pty Limited (Australia). A patient registry is an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s). *Gliklich and Dreyer, 2007: Registries for Evaluating Patient Outcomes.*