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New Investigator Led Study Examining the Combination of SIR-Spheres® Y-90 Resin Microspheres with Opdivo® in HCC

Sydney, Australia

Sirtex Medical Limited (ASX:SRX) today announces the launch of a new Investigator Initiated Trial (IIT) in non-resectable advanced hepatocellular carcinoma (HCC), the most common type of primary liver cancer. The study, known as NASIR-HCC, is a multi-centre, open label, single-arm study of the safety and anti-tumour efficacy of Opdivo® (nivolumab, Bristol-Myers Squibb Company) after SIR-Spheres microspheres for the treatment of patients with HCC that are candidates for loco-regional therapies. The primary endpoint is safety. Key secondary endpoints include Overall Survival (OS), Objective Response Rate (ORR), Disease Control Rate (DCR), Time to Progression (TTP) and Progression-Free Survival (PFS). The study is expected to recruit 40 patients.

The principal investigator of the study is Professor Bruno Sangro, Director of the Liver Unit at Clinica Universidad de Navarra, Spain. Sirtex is a financial sponsor of the study.

The scientific hypothesis underpinning the rationale for the study combination is that by inducing tumour cell death, SIR-Spheres may have a synergistic effect with immune checkpoint inhibitors by priming the immune system via the radiation-induced release of tumour antigens prior to treatment with nivolumab, which additionally takes the handbrake off immune system recognition of cancer cells.

Mr Andrew McLean, Chief Executive Officer of Sirtex Medical said "The NASIR-HCC study forms part of our clinical strategy that seeks to add value to our core product through small, targeted IITs using our therapy in combination with drug-based treatments like checkpoint inhibitors, which are in clinical development for a range of different cancer types, including HCC. This is the second IIT looking at this unique combination, with a similar study ongoing in Singapore."

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About NASIR-HCC

NASIR-HCC is a multi-centre open label, single-arm study of the safety and anti-tumoural efficacy of **N**ivolumab **A**fter **S**elective **I**nternal **R**adiation Therapy (SIRT) using SIR-Spheres for the treatment of patients with **H**epato**C**ellular Carcinoma that are candidates for locoregional therapies. The primary endpoint is to evaluate the safety of nivolumab in combination with SIRT using SIR-Spheres. Key secondary endpoints include Overall Survival (OS), Objective Response Rate (ORR), Disease Control Rate (DCR), Time to Progression (TTP) and Progression-Free Survival (PFS). The study is expected to recruit 40 patients.

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About Hepatocellular Carcinoma (HCC)

Hepatocellular Carcinoma (HCC) is the most common form of primary liver cancer – cancer that starts in the liver. It is the sixth most common cancer in the world and the second most common cause of cancer-related death[1].

About SIR-Spheres® Y-90 Resin Microspheres

SIR-Spheres Y-90 resin microspheres are a medical device used in interventional oncology and delivered via Selective Internal Radiation Therapy (SIRT), also known as radioembolisation, directly to liver tumours. SIR-Spheres Y-90 resin microspheres are approved for supply in key markets, such as the United States, European Union and Australia.

About Sirtex Medical, www.sirtex.com

Sirtex Medical Limited (ASX:SRX) is an Australian based medical device company with global market coverage. Its core revenue producing technology, which has regulatory approvals, is a selective internal radiation therapy (SIRT), with clinically proven applications for liver cancer with approximately 80,000 doses supplied and administered over 1,090 medical centres in more than 40 countries.

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[1] GLOBOCAN 2012. Estimated cancer mortality, incidence and prevalence worldwide. http://globocan.iarc.fr/Default.aspx