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RESIRT Clinical Data Presented at the 2016 ESMO Congress

Sydney, Australia; 10th October 2016 – Sirtex Medical Limited (ASX:SRX) is pleased to announce the initial safety and efficacy results from the RESIRT pilot clinical study in primary renal cell carcinoma (RCC, the most common form of kidney cancer) were presented in a poster session at the 2016 European Society for Medical Oncology (ESMO) Congress in Copenhagen, Denmark on Sunday, 9th October.

The RESIRT study is an Australian-based, single arm, dose escalation study in patients with RCC that were not suitable for curative therapy by surgical re-section, ablation or other conventional techniques. A total of 21 patients were treated with SIR-Spheres® Y-90 resin microspheres in a serial manner, across six dose-escalating cohorts with an intended radiation dose ranging from 75 Gray (Gy) to 300 Gy and an imminent stasis group. The primary endpoint of the study was safety and toxicity at 30 days post SIR-Spheres microspheres treatment.

In terms of safety data presented, the intended doses were delivered without any dose-limiting toxicity. Furthermore, there were no Serious Adverse Events or SAEs related to SIR-Spheres microspheres. 15/21 (71%) patients experienced 44 Adverse Events (AEs) within 30 days post SIR-Spheres microspheres treatment. Eight (38%) patients had AEs grade ≥3, all unrelated to SIR-Spheres microspheres; 8 patients (38%) had 12 AEs that were related to SIR-Spheres microspheres (all grade 1–2), of which 1 occurred pre SIR-Spheres microspheres.

In terms of initial efficacy of SIR-Spheres microspheres, the best overall tumour responses were: partial response 1/19 (5.3%), stable disease 17/19 (89.5%) and progressive disease 1/19 (5.3%).

The authors of the study concluded "This pilot study demonstrates good tolerability of SIRT at all dose levels including imminent stasis in treating primary tumours in RCC patients otherwise unsuitable for conventional therapy."

Dr David N. Cade, Chief Medical Officer of Sirtex Medical said "We are pleased with the initial results of the RESIRT study, given it represents our first clinical study investigating the use of SIR-Spheres microspheres outside of the liver. We look forward to examining the impact of our innovative intervention on survival outcomes in due course."

A copy of the abstract can be found at the following link (poster number **803P**, page 287):

http://www.esmo.org/content/download/88721/1622334/file/ESMO-2016-abstracts-excl-LBA-and-press-programme.pdf

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About RESIRT

A total of 21 patients were recruited serially into six dose escalating cohorts: 75 Gray (Gy), 100 Gy, 150 Gy, 200 Gy, and 300 Gy of intended radiation dose to tumour. The sixth cohort allowed the delivery of SIR-Spheres microspheres until cessation of blood flow in the renal artery. SIR-Spheres microspheres were administered once only with each patient receiving one allocated radiation dose. The primary endpoint of the study is safety and toxicity at 30 days, with secondary endpoints of tumour response rates, Progression-Free Survival (PFS), Overall Survival (OS) and Quality of Life (QoL). The study is listed on the Australian New Zealand Clinical Trials Registry (ANZCTR) under the identifier ACTRN12610000690055.

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

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. Over 67,000 doses have been supplied to treat patients with liver cancer at more than 1,000 medical centres in over 40 countries. For more information please visit www.sirtex.com.

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