



ASX / MEDIA RELEASE

11<sup>th</sup> October 2016

## Launch of a New Clinical Study in Cholangiocarcinoma and Incorporation into ESMO Clinical Practice Guidelines

**Sydney, Australia; 11<sup>th</sup> October 2016** – Sirtex Medical Limited (ASX:SRX) is pleased to announce the launch of a new randomised controlled clinical study of SIR-Spheres<sup>®</sup> Y-90 resin microspheres in patients with unresectable Intrahepatic Cholangiocarcinoma, also known as iCCA.

The study, known as SIRCCA, is a prospective, multi-centre, randomised, controlled clinical study evaluating SIR-Spheres<sup>®</sup> Y-90 resin microspheres preceding cisplatin-gemcitabine (CIS-GEM) chemotherapy versus CIS-GEM chemotherapy alone as a first-line treatment of patients with unresectable iCCA. Although a relatively rare disease, iCCA is the second most common form of primary liver cancer and starts in the bile duct, with an annual incidence of approximately 5,000 patients in the USA, which appears to be increasing.<sup>1</sup>

SIRCCA is expected to recruit 180 patients and is being conducted in 30 centres across Australia and Europe. The first patient is expected to be recruited into the study prior to the end of calendar year 2016, with the study anticipated to complete recruitment in late 2018.

Mr Gilman Wong, Chief Executive Officer of Sirtex Medical commented “The initiation of the SIRCCA study reflects the continued investment into our SIR-Spheres microspheres business to generate further clinical evidence to support new regulatory applications and product reimbursement. iCCA is a particularly attractive opportunity for Sirtex, where the use of our product has already shown promise and treatment options are very limited for these patients, while survival rates remain poor. This study, coupled with the inclusion of SIR-Spheres microspheres into the recent ESMO clinical practice guidelines for iCCA, will help us to build awareness and grow dose sales over time for this important disease.”

The European Society of Medical Oncology (ESMO) has recently highlighted the use of yttrium-90 (Y-90) microspheres for the treatment of iCCA following the publication of clinical practice guidelines on biliary cancers as a supplement to the *Annals of Oncology*.<sup>2</sup> Their lead author, Professor Juan Valle, department of medical oncology, Christie NHS Foundation Trust, University of Manchester, UK, states that selective internal radiation therapy (SIRT), which is also known as radioembolisation, “may be considered in patients with inoperable iCCA, usually after first-line chemotherapy.”

Dr David N. Cade, Chief Medical Officer of Sirtex Medical, said that “We are delighted to see SIR-Spheres<sup>®</sup> Y-90 resin microspheres cited as an important post-chemotherapy option for patients with locally advanced or metastatic iCCA, given no current standard of care exists beyond first-line treatment with cisplatin and gemcitabine chemotherapy in these patients. We believe that these are the first international clinical guidelines to include SIRT as a treatment option for patients with iCCA.”

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Dr Cade further commented “This new clinical practice guideline from ESMO comes at a significant time for Sirtex, given our new SIRCCA study across Europe and Australia. We anticipate the ESMO guideline will be an important catalyst to drive awareness on the use of SIR-Spheres microspheres in iCCA across Europe, and accordingly we would expect to receive a benefit in our ability to recruit patients onto the SIRCCA study. This study will be the largest ever interventional oncology study undertaken in this rare, but important disease, where prospective randomised data are lacking.”

## **About Cholangiocarcinoma**

Although relatively rare, cholangiocarcinoma is the world’s second most common form of primary liver cancer. In the westernized countries of Europe, North America and Australasia, cholangiocarcinoma incidence rates are low, with estimates ranging from 0.3 to 3.5 cases per 100,000 people annually. The intrahepatic form of cholangiocarcinoma (iCCA) is one of three types of the disease that physicians differentiate, primarily based on where the disease is located within the target organ. The other two forms are perihilar cholangiocarcinoma (pCCA), and distal cholangiocarcinoma (dCCA).

## **About SIRCCA**

The Selective Internal Radiation Therapy in Cholangiocarcinoma (SIRCCA) Study is a Phase II randomised clinical study for patients with intrahepatic cholangiocarcinoma (iCCA), a form of primary liver cancer that originates in the bile duct, a branching network of thin tubes that start in the segments of the liver and deliver fat-digesting bile to the small intestine. The SIRCCA study, sponsored by Sirtex, is designed to compare the effects of treating iCCA patients using the sequence of SIR-Spheres Y-90 resin microspheres followed by the standard-of-care cisplatin plus gemcitabine (CIS-GEM) chemotherapy versus CIS-GEM chemotherapy alone.

The primary endpoint of the study is Overall Survival at 18 months. Key secondary endpoints include Progression-Free Survival (PFS) in the liver, PFS at any site, Overall Survival, objective response rate, liver surgical resection and ablation rate and safety and tolerability. SIRCCA will enrol 180 patients at more than 30 treatment centres across Australia and several European countries, including Belgium, France, Germany, Italy, Spain, The Netherlands and UK. More information about SIRCCA can be found at <https://clinicaltrials.gov/ct2/show/NCT02807181>.

## **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](http://www.sirtex.com).

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<sup>1</sup> Bridgewater J, Galle PR, Khan SA *et al.* Guidelines for the diagnosis and management of intrahepatic cholangiocarcinoma. *J Hepatology* 2014; **60**: 1268-1289.

<sup>2</sup> Valle JW, Borbath I, Khan SA, Huguet F, Gruenberger T & Arnold D, On behalf of the ESMO Guidelines Committee. Biliary cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology* 2016; **27** (Suppl 5): v28–v37.