



ASX / MEDIA RELEASE

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SIRveNIB Clinical Study Completes Patient Recruitment

Sydney, Australia; 7th June 2016 – Sirtex Medical Limited (ASX:SRX) today announces the SIRveNIB clinical study in patients with unresectable primary liver cancer, also known as hepatocellular carcinoma or HCC, has completed patient recruitment.

Professor Pierce Chow, Principal Investigator of the SIRveNIB study, and Senior Consultant Surgeon at the National Cancer Centre Singapore and the Singapore General Hospital, explained that, “The search for more effective and better tolerated treatments of HCC is important, as so few proven treatment options currently exist. Beyond the primary endpoint of overall survival in SIRveNIB, we are also looking at a number of important secondary endpoints including a comparison of the side effects and patient quality of life with these two very different approaches to treating unresectable HCC. SIRveNIB is the largest Asia-Pacific study to directly compare SIRT and sorafenib, and indeed is the largest randomised study conducted on sorafenib in the region.”

Mr Gilman Wong, Chief Executive Officer of Sirtex Medical stated that “The use of liver-directed interventional procedures in the treatment of HCC in the Asia Pacific region is well-established in clinical practice. The SIRveNIB clinical study is specifically designed to examine the efficacy and safety of SIR-Spheres® Y-90 resin microspheres compared to sorafenib, the current standard of care systemic treatment in advanced HCC, in a predominately Asian population. Consequently, the generation of high quality Level 1 evidence arising from this study will be an important determinant in gaining accelerated adoption should the study deliver positive findings.”

The primary endpoint of the SIRveNIB study is Overall Survival (OS) with key secondary endpoints of quality of life and safety/tolerability. More than 360 patients were recruited into the study. The SIRveNIB study was conducted across 10 Asia-Pacific countries, including New Zealand with 27 centres participating.

Sirtex anticipates that the SIRveNIB study results will be available during the first half of calendar year 2017.

A copy of the Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC), National Cancer Centre Singapore, Singapore Clinical Research Institute (SCRI) and Sirtex joint release can be found at this link:

<http://www.prnewswire.com/news-releases/sirvenib-a-major-primary-liver-cancer-study-in-the-asia-pacific-region-completes-enrolment-581948551.html?a>

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About SIR_{ve}NIB

SIR_{ve}NIB is a Phase III Multi-Centre Open-Label Randomised Controlled Trial of Selective Internal Radiation Therapy (SIRT) using SIR-Spheres Y-90 resin microspheres Versus Sorafenib (Nexavar[®], Bayer HealthCare Pharmaceuticals, Germany) in Locally Advanced Hepatocellular Carcinoma. The primary objective of this study is to assess the efficacy of SIRT as compared with sorafenib in patients with locally advanced liver cancer in terms of overall survival (OS). ClinicalTrials.gov Identifier: NCT01135056. www.sirvenib.com.

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 death¹. Approximately 80% of the annual HCC incidence occurs in the Asia-Pacific region, where it is the third most common cancer.

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. Approximately 61,000 doses have been supplied to treat patients with liver cancer at more than 950 medical centres in over 40 countries. For more information please visit www.sirtex.com.

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¹ Ferlay J, Soerjomataram I, Ervik M *et al.* Globocan 2012. v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <http://globocan.iarc.fr>