



ASX / MEDIA RELEASE

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SARAH and SIR_veNIB Investigators to Undertake Combined Prospective Meta-Analysis

Sydney, Australia; 7th October 2016 – Sirtex Medical Limited (ASX:SRX) is pleased to announce that cancer researchers from Assistance Publique – Hôpitaux de Paris (AP-HP) and The Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC), National Cancer Centre Singapore and Singapore Clinical Research Institute (SCRI) intend to collaborate on a prospective meta-analysis that will combine the impending results of two large, randomized controlled studies of SIR-Spheres[®] Y-90 resin microspheres versus sorafenib (Nexavar[®], Bayer HealthCare Pharmaceuticals, Germany). The two studies, SARAH and SIR_veNIB, have completed patient recruitment and enrolled over 800 patients with inoperable primary liver cancer, also known as hepatocellular carcinoma (HCC). Results of the prospective meta-analysis are expected to be available during calendar year 2017.

Mr Gilman Wong, Chief Executive Officer of Sirtex Medical remarked “We are very pleased that the SARAH and SIR_veNIB study investigators have decided to collaborate and combine their two studies in a prospective meta-analysis. This is a unique opportunity given the individual studies are now both expected to report their results within the same timeframe during the first half of calendar year 2017 and demonstrates considerable foresight by the investigators as most meta-analyses are performed retrospectively.”

A prospective meta-analysis is initiated when two or more randomised studies have been identified, evaluated and determined to be eligible for the meta-analysis before the results of any of those studies is known.¹

Dr David N. Cade, Chief Medical Officer of Sirtex Medical explained “By combining the SIR_veNIB and SARAH studies in a prospective manner in a meta-analysis, the clinical data thus generated will be of a higher level of scientific evidence than either of the individual SARAH or SIR_veNIB randomised controlled studies alone. This enables the investigators to draw more robust conclusions on Overall Survival, as well as a number of important pre-planned subgroups including those patients who have received prior trans-arterial chemoembolisation (TACE) and those with invasion of their disease into the portal vein. Such an *a priori* or prospective analysis is a widely accepted scientific approach in fully appraising the outcomes of similarly designed clinical studies.”

Further details regarding the methodological and statistical approach to the meta-analysis are to be published in a peer-reviewed journal in advance of the actual meta-analysis findings.

Professor Pierce Chow, Principal Investigator of the SIR_veNIB study, and Senior Consultant Surgeon at the National Cancer Centre Singapore and the Singapore General Hospital, explained that, “As we stated when we first announced completion of enrolment in SIR_veNIB, the search for more effective and better tolerated treatments of HCC is important because so few proven treatment options currently exist. Our study enrolled more than 360 patients from 27 specialist centres in 10 Asia-Pacific countries. While our

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data will be reported independently, the opportunity to combine these data in a prospective meta-analysis with the results of the French SARAH study presents a compelling scientific undertaking across a much larger patient population that will significantly increase the data available for various pre-planned statistical analyses, including overall survival. This should provide physicians who treat HCC with even greater certainty of the applicability of our results in the treatment of this increasingly common and deadly cancer.”

Professor Valérie Vilgrain MD, PhD, Principal Investigator of the SARAH study, Head of Department of Radiology, Beaujon Hospital, AP-HP and Professor at the Université Paris Diderot, Sorbonne Paris Cité, France, said that “The SARAH study was conducted in more than 25 specialist centres throughout France and is expected to report results in the first half of 2017. While we will also report the results of SARAH independently, we believe a prospective meta-analysis of our findings combined with those of the SIR_{ve}NIB study may be very compelling. HCC in France and most of Europe is found in patients whose livers have become cirrhotic primarily from the Hepatitis C virus and alcohol misuse, while the majority of HCC cases in Asia are triggered initially by the Hepatitis B virus. Thus, our prospective meta-analysis will provide safety and efficacy data on patients who presented with a full range of the major HCC aetiologies, potentially increasing the clinical applicability of the study results.”

A copy of the joint investigator release can be found at the following link:

<http://www.prnewswire.co.uk/news-releases/liver-cancer-researchers-from-ap-hp-and-singapore-collaborate-on-a-prospective-meta-analysis-of-two-studies-of-y-90-resin-microspheres-versus-sorafenib-in-patients-with-unresectable-hepatocellular-carcinoma-hcc-596114101.html>

About SARAH

SARAH (SorAfenib versus Radioembolisation in Advanced Hepatocellular carcinoma) is a Phase III multi-centre prospective randomised open-label study for patients in France with advanced HCC (Barcelona Clinic Liver Cancer stage C) with or without portal vein thrombosis and no extrahepatic spread, or whose disease has progressed or recurred after previous therapies; and who are ineligible for surgical resection, ablation or liver transplantation.

The primary goal of the SARAH study is to assess if radioembolisation with SIR-Spheres Y-90 resin microspheres provides an increased survival benefit compared to Sorafenib (Nexavar[®], Bayer HealthCare Pharmaceuticals, Germany) in patients with advanced HCC. The study is also comparing the quality of life of patients and other measures such as the tolerability of the treatments and healthcare costs associated with each intervention. For more information on the SARAH study, please visit: <http://clinicaltrials.gov/ct2/show/NCT01482442>.

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 death². 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. 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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¹ Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0. Editors: Higgins, JPT and Green, S.

² 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>