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Combined SARAH/SIR*ve*NIB Meta-Analysis Study 'VESPRO' Published

Sydney, Australia; 17th February 2017 – Sirtex Medical Limited (ASX:SRX) today announces that the protocol for the combined prospective meta-analysis of the SARAH and SIR*ve*NIB studies, known as the SIR*ve*NIB and SARAH merge project (**VESPRO**) has been published in the *Journal of Medical Internet Research (JMIR) Research Protocols.*

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]. The VESPRO collaboration between the SARAH and SIR*ve*NIB study investigators was announced by Sirtex in October, 2016. Both studies are directly comparing SIR-Spheres® Y-90 resin microspheres with sorafenib (Nexavar®, Bayer Healthcare Pharmaceuticals).

The study authors concluded "As the results of the 2 trials are not yet known, the methodological strength is enhanced, as biases inherent in conventional meta-analyses are avoided. This has the effect of providing this meta-analysis with the advantages of a single, large, randomized study of 819 patients. It is anticipated that the SARAH and SIR*ve*NIB trial results will be published separately and together with the combined meta-analysis results from VESPRO. The combined dataset will allow the effect of the interventions to be explored with improved reliability/precision with the respect to pre-specified patient and intervention-level characteristics."

Mr Nigel Lange, Interim Chief Executive Officer of Sirtex Medical commented "The publication of the VESPRO study protocol ensures complete transparency of the combined prospective meta-analysis methodology. The statistical power that arises from the combination of the SARAH and SIR*ve*NIB studies into this meta-analysis allows for increased precision in determining survival outcomes when performing various subgroup analyses including patients who have received prior trans-arterial chemoembolisation (TACE) and those with invasion of their disease into the portal vein. Furthermore, the investigators inclusion of a non-inferiority or NI analysis into the study design provides the ability to assess the merits of the SIR-Spheres microspheres therapy versus that of sorafenib from a toxicity and cost perspective in the event that efficacy is similar. Such design considerations will enhance the quality of information provided to clinicians to make informed decisions about treatment for patients suffering with hepatocellular carcinoma or HCC."

Results of the prospective meta-analysis are expected to be available during calendar year 2017.

A copy of the JMIR publication can be sourced from the following link:

http://www.researchprotocols.org/2017/2/e17/

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About VESPRO

The SIR*ve*NIB and SARAH merge project (VESPRO) is a prospective meta-analysis of Selective Internal Radiation Therapy (SIRT) versus Sorafenib for Hepatocellular Carcinoma including the SARAH and SIR*ve*NIB studies on 819 patients. The primary endpoint of the study is overall survival assessed by review of the SARAH and SIR*ve*NIB study data. Secondary endpoints include progression in the liver, overall progression-free survival, tumour response rate, disease control rate and toxicity.
https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12617000030370

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). For more information on the SIRveNIB study visit: http://clinicaltrials.gov/ct2/show/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 death[2]. 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 73,000 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 Sytematic 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