ASX/MEDIA RELEASE **13 April 2018**

SORAMIC CLINICAL STUDY RESULTS TO BE PRESENTED AT EASL/ILC

- **Study did not meet the primary endpoint of an Overall Survival (OS) benefit of SIR-Spheres® Y-90 resin microspheres plus sorafenib versus sorafenib alone**
- **Sub-group analyses of the Per-Protocol (PP) population suggested an OS benefit of SIR-Spheres + sorafenib in patients ≤ 65 years of age, non-cirrhotics and non-alcoholic aetiology**
- **Results to be presented on Saturday, 14 April at the European Association for the Study of the Liver (EASL), The International Liver Congress™ 2018 in Paris, France**[1]

Sydney, Australia

Sirtex Medical Limited (ASX:SRX) today announces the results of the 424 patient SORAMIC clinical study comparing SIR-Spheres® Y-90 resin microspheres plus the current standard-of-care systemic therapy sorafenib (Nexavar®, Bayer Healthcare Pharmaceuticals) versus sorafenib alone in patients with non-resectable advanced hepatocellular carcinoma (HCC), the most common type of primary liver cancer.

The study authors concluded "The addition of SIRT to sorafenib did not result in a significant improvement in overall survival compared to sorafenib alone. Subgroup analyses led to hypothesis generating results for patient groups with potential clinical benefit."

Mr Andrew McLean, Chief Executive Officer of Sirtex Medical said "While we are disappointed the study did not meet the primary endpoint of an OS advantage versus sorafenib alone, we continue to focus on executing our multi-tiered growth strategies for SIR-Spheres microspheres, while prudently managing operating expenditures. It is important to note the outcomes from this study in no way effects Sirtex's financial position as the capitalised costs of this study were written-off in June 2017 and the results have no bearing on the proposed acquisition of Sirtex by Varian Medical Systems, Inc., which is due to be implemented on 25 May 2018."[2]

The study will be presented as an oral abstract entitled "The impact of combining Selective Internal Radiation Therapy (SIRT) with Sorafenib on overall survival in patients with advanced hepatocellular carcinoma: The SORAMIC trial palliative cohort."

Professor Jens Ricke, Principal Investigator of the SORAMIC study from the Ludwig-Maximilians University Munich, Department of Radiology, Munich, Germany said "'Although we were disappointed to find no overall survival benefit of adding SIRT to sorafenib across the entire study population, we did observe a survival benefit in younger patients, those with non-alcoholic aetiology of the cirrhosis, and those with no cirrhosis at all."

A summary of the key findings:

In the Intent-to-Treat (ITT) palliative treatment cohort, 216 patients were randomised to SIR-Spheres microspheres + sorafenib and 208 to sorafenib alone. Median OS was 12.1 months (95% confidence interval [CI], 10.6–14.6) in the SIR-Spheres microspheres + sorafenib arm, and 11.5 months (95% CI, 9.8–13.9) in the sorafenib arm (hazard ratio [HR], 1.01; 95% CI, 0.82–1.25; p=0.93).

In the PP group, median OS was 14.1 months (95% CI, 10.9–16.4) in the SIR-Spheres microspheres + sorafenib arm (n=114), and 11.1 months (95% CI, 9.7–13.9) in the sorafenib arm (n=174; HR, 0.86; 95% CI, 0.67–1.11; p=0.25).

Subgroup analyses of the PP population suggested a survival benefit for patients receiving SIR-Spheres microspheres + sorafenib ≤ 65 years (HR, 0.65; 95% CI 0.43–1.00, p=0.05); non-cirrhotics (HR, 0.465; 95% CI 0.25–0.86, p=0.02); and non-alcoholic aetiology (HR, 0.63; 95% CI 0.45–0.89, p=0.01).

Adverse events (AEs) of Common Terminology Criteria for AE Grade ≥3 were reported in 115/159 (72.3%) patients in the SIR-Spheres microspheres + sorafenib arm and 135/197 (68.5%) patients in the sorafenib arm.

A press release on the SORAMIC study has been issued by the ILC press office: https://ilc-congress.eu/ilc-2018-press-kit/

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About SORAMIC

SORAMIC is the first large randomised controlled trial (RCT) to compare the efficacy and safety of combining sorafenib and SIR-Spheres® Y-90 resin microspheres versus sorafenib alone in the treatment of HCC in the palliative cohort. Patients with HCC who took part in the palliative cohort of the SORAMIC study were not eligible for resection or ablation, and were not ideal candidates for transarterial chemoembolisation (TACE).

The primary endpoint of the palliative arm of the SORAMIC study is Overall Survival (OS). Secondary endpoints include Safety and OS for patients with and without portal vein thrombosis. For more information on the SARAH study, please visit: https://clinicaltrials.gov/ct2/show/results/NCT01126645.

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[3].

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, www.sirtex.com

Sirtex Medical Limited (ASX:SRX) is an Australian based medical device company with global market coverage. Its core revenue producing technology, which has regulatory approvals, is a selective internal radiation therapy (SIRT), with clinically proven applications for liver cancer with over 86,000 doses supplied and administered at over 1,160 medical centres in more than 40 countries.

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[1] Ricke *et al*. The International Liver Congress™ 2018 – 53rd annual meeting of the European Association for the Study of the Liver, *Journal of Hepatology* 2018; **68** (Suppl 1): Abs. LBO-005.

[2] All dates are indicative only and are subject to the Court approval process and the satisfaction or, where applicable, waiver of conditions precedent under the Scheme. Any changes to the above timetable will be announced by Sirtex to ASX.

[3] GLOBOCAN 2012. Estimated cancer mortality, incidence and prevalence worldwide. http://globocan.iarc.fr/Default.aspx