ASX/MEDIA RELEASE **18th May 2017**

SIR*ve*NIB Study Shows Statistically Significant Safety and Toxicity Benefit for SIR-Spheres versus Sorafenib with Similar Overall Survival in HCC

- **In patients receiving treatment (Per-Protocol, PP)[1] median Overall Survival (OS) in SIR-Spheres® Y-90 resin microspheres arm of 11.3 months versus 10.4 months for sorafenib was not significantly different (Hazard Ratio (HR)=0.86; p=0.273)**
- **In patients randomised to receive treatment (Intention-To-Treat, ITT)[2] the median OS in the SIR-Spheres arm was 8.5 months versus 10.6 months in the sorafenib arm was not significantly different (HR=1.17; p=0.203)**
- **Statistically significant safety and toxicity benefits favouring SIR-Spheres**

Sirtex will host an **Investor Conference Call** to discuss the SIR*ve*NIB and SIRFLOX/FOXFIRE/FOXFIRE Global clinical study results, including a Q&A session at **1:00 pm AEST today**.
Conference ID: 1973 1589
Toll Free Dial-in Details: Australia Toll Free: 1800 123 296, Australia Local Dial: +61 2 8038 5221, USA: 1855 293 1544, United Kingdom 0808 234 0757 (other countries – see end of release)

Sydney, Australia; 18th May 2017 – Sirtex Medical Limited (ASX:SRX) today announces the results of the 360 patient SIR*ve*NIB clinical study comparing SIR-Spheres® Y-90 resin microspheres versus sorafenib (Nexavar®, Bayer Healthcare Pharmaceuticals) in patients with non-resectable advanced hepatocellular carcinoma (HCC), the most common type of primary liver cancer. The study was conducted in predominately Asian patients, across 11 Asian countries and New Zealand, with 27 centres participating. The abstract was published on-line ahead of the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

While the primary endpoint of Overall Survival (OS) superiority versus sorafenib in the Intent to Treat analysis was not met, the SIR*ve*NIB study showed both treatments resulted in a similar median OS in patients with statistically significant safety and toxicity favouring SIR-Spheres.

Mr Nigel Lange, Interim CEO of Sirtex Medical said "We are particularly pleased with the SIRveNIB study results. The results demonstrate that SIR-Spheres minimise the adverse effects that otherwise would diminish the quality of liver cancer patients' survival. In addition, SIR-Spheres delivered survival outcomes that were not statistically different versus sorafenib, the only approved first-line agent for advanced HCC. We note that 29% of patients did not receive SIR-Spheres in the ITT analysis and this clearly impacted the overall survival result when compared to the overall survival data from the PP analysis. The results of SIR*ve*NIB support similar findings in in the SARAH study, as recently reported at the EASL International Liver Congress™ 2017."

Mr Lange continued "Our Asian business continues to perform to plan throughout FY17, and following peer review and acceptance at ASCO, we believe SIR*ve*NIB will generate further awareness and interest in SIR-Spheres from clinicians seeking a well-tolerated alternative treatment to sorafenib in advanced HCC patients. We therefore eagerly await the oral abstract presentation at ASCO by Professor Chow on the 4th of June."

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The SIR*ve*NIB study is the largest ever randomised controlled trial in a predominately Asian population to provide Level 1 evidence demonstrating that a liver-directed therapy, namely SIR-Spheres Y-90 resin microspheres, was not statistically different in overall survival outcomes compared to the standard of care chemotherapy agent sorafenib.

The study authors concluded "*Asian patients with locally advanced HCC without extra-hepatic metastasis treated with Y90 have statistically significant better TRR [Tumour Response Rate], and fewer SAEs [Serious Adverse Events] when compared with those treated with sorafenib. There were no statistically significant differences in OS between Y90 and sorafenib*."

A summary of the key findings of the SIR*ve*NIB abstract[3] were as follows:

- Intention-to-treat analysis was carried out with the overall survival (OS) in the SIR-Spheres and sorafenib arms being 8.54 and 10.58 months respectively (Hazard ratio (HR) =.17, p = 0.203).
- Tumour response rate (TRR) was 16.5% and 1.7% (p < 0.001) in the SIR-Spheres and sorafenib arms, respectively.
- Altogether 28.6% and 9.0% of patients in the SIR-Spheres and sorafenib arms respectively failed to receive planned therapy.
- BCLC C patients without extra-hepatic metastasis comprised 41.4% of patients, 30.6% had portal vein thrombosis (PVT), 88.6% were Child-Pugh A, 57.2% were hepatitis B and 15.0% were hepatitis C.
- At least one severe adverse event was found in 27.7% and 50.6% of patients in the SIR-Spheres and sorafenib arms, respectively.
- Time-to-tumour-progression (TTP) was 5.88 vs 5.36 (overall) (HR=0.93) and 6.08 vs 5.39 (liver-specific) (HR=0.91) months for SIR-Spheres and sorafenib, respectively.
- Progression-free-survival (PFS) was 5.29 vs 5.06 (overall) (HR=0.94) and 5.85 vs 5.06 (liver-specific) (HR=0.92) months respectively.

The SIR*ve*NIB study abstract is available through the ASCO website:
http://abstracts.asco.org/199/AbstView_199_187604.html

Conference Call Details:

Time: 1:00 pm AEST today.

Participants are encouraged to register at least 5-10 minutes prior to the commencement of the call, using the details provided, below.

Conference ID: 1973 1589

Toll Free Dial-in Details:
Australia Toll Free: 1800 123 296
Australia Local Dial: +61 2 8038 5221
USA: 1855 293 1544
Hong Kong: 800 908 865
Singapore: 800 616 2288
United Kingdom: 0808 234 0757
New Zealand: 0800 452 782
Canada: 1855 5616 766
Japan: 0120 477 087

A recording of the call will be made available in the 'Investors' section of the Company website shortly after the conclusion of the call at: http://www.sirtex.com/au/investors/

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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 death[4].

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 1,060 medical centres in over 40 countries. For more information please visit www.sirtex.com.

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[1] **Per-Protocol (PP)** analysis is a comparison of treatment groups that includes only those patients who completed the treatment originally allocated. The PP analysis for SIR*ve*NIB included n=130 (SIR-Spheres arm) and n =162 (sorafenib arm).

[2] **Intention-To-Treat (ITT)** analysis is where all patients who were enrolled and randomly allocated to treatment are included in the analysis and are analysed in the groups to which they were randomised. The intent-to-treat-group included n=182 (SIR-Spheres) and n=178 (sorafenib).

[3] Chow PKH *et al.* Phase III multi-centre open-label randomized controlled trial of selective internal radiation therapy (SIRT) versus sorafenib in locally advanced hepatocellular carcinoma: The SIRveNIB study. *2017 ASCO Annual Meeting; J Clin Oncol* 2017; **35** (Suppl): Abs 4002.

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