Sirtex Reports Preliminary SIRFLOX Study Results

- ***In the first-line treatment of non-resectable metastatic colorectal cancer:***
  - ***SIRFLOX study does not show a statistically significant improvement in overall Progression-Free Survival.***
  - ***SIRFLOX study does show a statistically significant improvement in Progression-Free Survival in the liver.***
- ***Data to be submitted for peer review to the American Society of Clinical Oncology (ASCO) 2015 Annual Meeting***

Sydney, Australia; 17th March 2015 -- Sirtex Medical Limited (ASX: SRX) is pleased to report today the preliminary results of its SIRFLOX clinical study.

Based on the preliminary analysis just completed, the primary endpoint of the SIRFLOX study was not achieved. The preliminary analysis shows that adding SIR-Spheres® Y-90 resin microspheres to a current first-line systemic chemotherapy regimen for the treatment of non-resectable metastatic colorectal cancer (mCRC) does not result in a statistically significant improvement in the overall Progression-Free Survival (PFS). Overall PFS measures progression of existing tumours and/or the development of new tumours in any organ or body site.

Sirtex is pleased that the preliminary analysis showed that SIR-Spheres Y-90 resin microspheres did result in a statistically significant improvement in Progression-Free Survival (PFS) in the liver. This secondary study endpoint is important as liver tumours are commonly the only, or dominant, site of disease in patients with mCRC and are the major site of disease influencing survival. Up to 90% of mCRC patients die of liver failure due to the local effects of the liver tumours[(1)]. SIR-Spheres Y-90 resin microspheres are specifically targeted to treat liver tumours.

As previously advised (most recently on 9th October 2014), the SIRFLOX study results and preliminary analysis still require verification and validation through the process of academic peer review. Presentation at a scientific conference and/or publication in a medical journal are essential parts of this process.

The final results and related detailed analysis of the SIRFLOX study will therefore be submitted to the American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held 29th May – 2nd June 2015 in Chicago, Illinois.

About the SIRFLOX Study

The SIRFLOX study is an international, multi-centre, randomised controlled study that enrolled over 500 patients with mCRC whose disease was non-resectable and had spread to either the liver alone or the liver plus a limited number of sites outside the liver, including lymph nodes and the lungs. Patients were randomised to receive either a current first-line systemic chemotherapy regimen using FOLFOX (folinic acid, 5-fluorouracil and oxaliplatin) with the option to receive bevacizumab (Avastin®) or the same chemotherapy with the addition of a single administration of SIR-Spheres Y-90 resin microspheres.

The study was conducted in more than 100 hospitals across Australia, Europe, Israel, New Zealand and the United States.

For information, please visit www.sirflox.com, and the ASX announcement made by the Company on October 9th 2014.

About Sirtex Medical Limited
For information, please visit www.sirtex.com

SIR-Spheres® is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd.

Reference:

(1) Kennedy A; Coldwell D *et al.* Resin ^{90}Y-microsphere brachytherapy for non-resectable colorectal liver metastases: modern USA experience. *Int. J. Radiation Oncology Biol. Phys* 2006; **65** (2): 412-425.

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