FOXFIRE Global Study Completes Patient Recruitment

Sydney, Australia; 8th January 2015 – Sirtex Medical Limited (ASX:SRX) is pleased to announce the completion of patient recruitment in the FOXFIRE Global randomised controlled clinical study comparing SIR-Spheres® Y-90 resin microspheres in combination with standard of care chemotherapy versus chemotherapy alone in first-line metastatic colorectal cancer (mCRC) in patients with inoperable liver metastases.

The SIRFLOX, FOXFIRE and FOXFIRE Global clinical studies recruited over 1,000 patients globally. The primary endpoint of Overall Survival (OS) from the combined studies is anticipated to be available during 1H CY17.

Mr Gilman Wong, CEO of Sirtex Medical commented “We are delighted to have completed recruitment of our FOXFIRE Global clinical study on schedule with the total number of patients recruited ahead of initial expectations under the study design. This study, when combined with the FOXFIRE clinical study conducted in the UK by the University of Oxford and our own SIRFLOX clinical study will generate sufficient statistical power to determine whether SIR-Spheres® microspheres in combination with existing chemotherapy can increase Overall Survival in a clinically significant manner in these patients versus chemotherapy alone. We wish to thank the patients, physician investigators and research staff involved with the FOXFIRE Global study.”

The FOXFIRE Global study recruited over 200 patients globally. The FOXFIRE study, which completed recruitment in October 2014, recruited over 360 patients across 32 centres in the UK. Collectively, the two studies recruited approximately 17% more patients than originally envisaged under the respective study designs, driven largely by the accelerated recruitment of the FOXFIRE Global study.

About FOXFIRE Global

FOXFIRE global is a multi-centre, randomised controlled study that will assess the efficacy, in terms of Overall Survival (OS), of adding targeted radiation, in the form of SIR-Spheres® microspheres, to a standard chemotherapy regimen of FOLFOX6m as first-line therapy in patients with non-resectable liver metastases from primary colorectal carcinoma. The study is designed to allow for a combined analysis with clinical data from the SIRFLOX and FOXFIRE studies. The total sample size in the 3 studies combined will be at least 1,020 patients, which provides adequate power to detect a clinical significant difference in Overall Survival between the experimental and control arms. FOXFIRE Global is being conducted at sites across Australia, New Zealand, Asia, Europe, the Middle East and USA.

For further information, please visit http://foxfireglobal.sirtex.com.
For further information on the FOXFIRE clinical study, please visit http://www.octo-oxford.org.uk/alltrials/infollowup/FOXFIRE.html.

For further information on the SIRFLOX clinical study, please visit http://www.sirflox.com/home.

**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 called SIR-Spheres® Y-90 resin microspheres. More than 45,000 doses have been supplied to treat patients with liver cancer at more than 700 medical centres in over 30 countries. SIR-Spheres® microspheres are a medical device used in interventional oncology and delivered to the liver via Selective Internal Radiation Therapy (SIRT).

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