FOXFIRE and FOXFIRE Global Studies Complete Patient Enrolment

Combined data from more than 1,000 patients being collected to assess overall survival (OS) benefit of adding first-line SIR-Spheres® Y-90 resin microspheres treatment to a current chemotherapy regimen for inoperable metastatic colorectal cancer (mCRC)

Sydney, Australia (29 January 2015) -- Sirtex Medical Limited (ASX:SRX) today announced the completion of patient enrolment in FOXFIRE and FOXFIRE Global, two large multi-centre studies that added liver-directed radiation therapy with SIR-Spheres Y-90 resin microspheres to a current standard of care chemotherapy regimen in the first-line treatment of more than 560 patients recently diagnosed with inoperable metastatic colorectal cancer (mCRC).

By previous design, the data of FOXFIRE and FOXFIRE Global will be combined with the findings of 500-patient SIRFLOX study to form a database of more than 1,000 patients that has sufficient statistical power to evaluate whether first-line SIR-Spheres microspheres in combination with a standard-of-care chemotherapy versus chemotherapy alone can significantly increase the Overall Survival of patients with colorectal cancer liver metastases. The results of this combined study are expected to be known in the first half of 2017.

"We are very pleased that FOXFIRE and FOXFIRE Global have so quickly reached their ambitious enrolment goals," said Gilman Wong, CEO of Sirtex Medical Limited. "Announcing the results of the earlier SIRFLOX study remains our immediate priority. However, the fact that enrolment in all three studies is now complete presents us an unprecedented opportunity to demonstrate the important role that SIR-Spheres microspheres may play in the treatment of patients with mCRC, for whom liver tumours are all too often the greatest cause of failing health. We are grateful to the many doctors, nurses and other medical staff, and especially the patients and their families who have made this important undertaking possible."

The FOXFIRE Study, which enrolled more than 360 patients in 32 UK cancer centres, was initiated in 2008 by the Oxford Oncology Clinical Trials Office (OCTO) in collaboration with the UK National Cancer Research Institute. It is sponsored by the University of Oxford, and funded by the Bobby Moore Fund for Cancer Research UK, the Experimental Cancer Medicine Centre (ECMC) Network and Sirtex.

The FOXFIRE chief investigators are Professor Ricky Sharma, Consultant Clinical Oncologist at the Oxford University Hospitals NHS Trust, and Dr. Harpreet Wasan, Consultant and Reader in Medical Oncologist, Imperial College Healthcare, Hammersmith Hospital, London.

"Despite significant advances we have made in treating this disease with chemotherapy and biologically targeted therapies, optimising the care for patients with colorectal cancer that has spread to the liver remains a significant challenge in oncology," Professor Sharma said. "For rectal cancer, the combination of radiotherapy and chemotherapy is an established standard of care. Treating the liver with the same combination of treatments has been difficult due to the sensitivity of healthy liver tissue to radiotherapy. These exciting clinical trials combine a safe form of internally administered radiotherapy with routine chemotherapy. Recruiting over 1,000 patients to these trials represents an important step forward in determining whether targeting these tumours with both treatments acting together is better than using chemotherapy on its own."

Dr. Wasan adds that "This is the reason why we needed to conduct definitive research in the early use of liver-directed radiotherapy with SIR-Spheres Y-90 resin microspheres in these patients. Completing enrolment in the FOXFIRE study is an important milestone in our work to address whether adding selective internal radiation therapy to first-line chemotherapy will provide an important gain in Overall Survival for patients with colorectal cancer liver metastases."

FOXFIRE Global, which enrolled more than 200 patients and was funded by Sirtex, began in 2013 in a network of more than 80 centres in Australia, New Zealand, Asia Pacific, Israel, Western Europe and the United States.

The principal investigator of FOXFIRE Global is Professor Peter Gibbs, Associate Professor of Medical Oncology at the Royal Melbourne Hospital and Western Hospital, Melbourne, Australia.

"Completing these three studies was an enormous undertaking, but it is no less enormous than the need for more effective ways to treat colorectal cancer that has metastasised to the liver, which is the most common site of its spread and affects several hundred thousand patients worldwide each year," Professor Gibbs explained. "Obviously, we do not yet know if this combination of chemo-radiotherapy will prove successful in early treatment of mCRC, but we do know from published data that mCRC patients who no longer respond to chemotherapy have already benefitted from selective internal radiation therapy, or SIRT, as it is more widely known."

Sirtex invested a total of AUD $22 million into its clinical programmes during FY14.

About FOXFIRE and FOXFIRE Global

The primary objective of the FOXFIRE and FOXFIRE Global studies is to determine if there is an Overall Survival benefit of adding targeted radiation, in the form of SIR-Spheres Y-90 resin microspheres, to a current standard-of-care systemic chemotherapy regimen compared to chemotherapy alone in patients with inoperable liver metastases from primary colorectal cancer, with or without evidence of metastases outside the liver. In both studies, the chemotherapy regimen

used is FOLFOX (oxaliplatin plus 5FU and leucovorin), with or without the biologic agents bevacizumab or cetuximab (prescribed at the investigators' discretion).

The FOXFIRE and FOXFIRE Global studies were designed from the outset to allow for a combined analysis together with the clinical data from the SIRFLOX study. The total sample size in the three studies combined will be at least 1,000 patients, which provides adequate statistical power to detect a clinical significant difference in Overall Survival between the experimental and control arms. For further information, please visit http://www.octo-oxford.org.uk/alltrials/infollowup/FOXFIRE.html and http://foxfireglobal.sirtex.com.

About Colorectal Cancer

Colorectal cancer (CRC or bowel cancer) occurs when cancerous cells develop in the patient's colon or rectum. CRC is the third most common form of cancer worldwide, making up about 10% of all cancers. In 2012, an estimated 1.4 million new cases were diagnosed globally and 694,000 cancer deaths were attributed to CRC[1].

Surgery, radiation and chemotherapy are the main treatments for CRC itself. However, despite the best of treatments, CRC can spread (or metastasise) to other parts of the body, resulting in metastatic colorectal cancer, or mCRC. Approximately 50 percent of patients will be diagnosed with mCRC either at the time of initial diagnosis or due to recurrent disease. The liver is the most frequent site of mCRC and unfortunately the majority of patients are inoperable at diagnosis due to the extent of their disease. Liver failure due to the uncontrolled growth of metastases in the liver is the most common cause of eventual death.

About SIR-Spheres Y-90 resin microspheres

SIR-Spheres Y-90 resin microspheres are a medical device used in interventional oncology to deliver Selective Internal Radiation Therapy or SIRT (also known as radioembolisation), a proven technology for inoperable liver tumours that delivers substantial, targeted doses of radiation directly to the cancer. In a minimally invasive treatment, millions of SIR-Spheres Y-90 resin microspheres are infused via a catheter into the liver where they selectively target liver tumours with a dose of internal radiation up to 40 times higher than conventional radiotherapy, while sparing the adjacent healthy liver tissue.

Manufactured by Sirtex Medical Limited, SIR-Spheres Y-90 resin microspheres are approved in Australia, the European Union (CE Mark), Argentina (ANMAT), Brazil, Switzerland, Turkey and several other countries in Asia such as India, Korea, Singapore, and Hong Kong for the treatment of liver tumours that are unable to be removed through surgery.

SIR-Spheres Y-90 resin microspheres also have a full Pre-Market Approval (PMA) from the US FDA and are indicated in the United States for the treatment of non-resectable metastatic liver tumours from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using

floxuridine. Additionally, SIR-Spheres microspheres are supplied in countries such as Israel, Malaysia, New Zealand, Taiwan and Thailand.

Available at more than 700 treatment centres, over 45,000 doses of SIR-Spheres microspheres have been supplied worldwide.

About Sirtex Medical Limited

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 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. For further information please visit www.sirtex.com.

References:

1. World Cancer Report, 2014; Geneva, WHO: 2014.

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985-EUA-0115