



## **New SIRFLOX Study Data Presented at World Congress of Gastrointestinal Cancer**

### ***Adding SIR-Spheres® Y-90 resin microspheres to first-line chemotherapy for patients with unresectable metastatic colorectal cancer in the liver (mCRC) further extends Progression-Free Survival in that organ***

Barcelona, Spain (4 July 2015) – Patients with unresectable metastatic colorectal cancer (mCRC) that has spread only to the liver experienced the greatest improvement in Progression-Free Survival (PFS) in the liver from the addition of SIR-Spheres Y-90 resin microspheres to a current first-line chemotherapy regimen, according to new data from the SIRFLOX study presented at the European Society for Medical Oncology (ESMO) 17<sup>th</sup> World Congress of Gastrointestinal Cancer (WCGIC).

The new findings from the 530-patient SIRFLOX randomized controlled study were presented by Prof. Guy van Hazel, co-principal investigator of the SIRFLOX study and Clinical Professor of Medicine at the University of Western Australia, Perth, Australia.

“As our group reported earlier at the 2015 ASCO meeting in Chicago, liver tumours began to grow again after a median of 12.6 months in patients with mCRC who received only first-line chemotherapy, even with the optional addition of bevacizumab, while those who also received first-line treatment with SIR-Spheres Y-90 resin microspheres reached a median of 20.5 months before their liver disease progressed. This additional 7.9 month added treatment benefit represents a significant 31 percent reduction in the risk of tumour progression in the liver for patients treated with SIR-Spheres Y-90 resin microspheres. This finding applied to all patients in the study, whether they had metastases only in the liver or in other sites as well,” Prof. van Hazel said.

“Our new analyses focused on the impact of two important factors on this treatment benefit. The first of these is that among the 318 patients with metastases that had spread only to the liver at the time they entered the study, median PFS in the liver was 21.1 months for those treated with SIR-Spheres plus chemotherapy, compared to 12.4 months for those treated with chemotherapy alone. This 8.7 month improvement was statistically significant ( $p$ -value = 0.003, with a hazard ratio of 0.64) and represents a notable 36 percent reduction in the risk of tumour progression in the liver,” Professor van Hazel explained.

Professor van Hazel also disclosed new findings regarding the impact of bevacizumab in the chemotherapy regimen used in the SIRFLOX study. “In both groups – the 292 patients who had an intention to treat using bevacizumab in addition to first-line mFOLFOX6 chemotherapy, and the 238 who did not – the addition of SIR-Spheres Y-90 resin

microspheres resulted in a statistically significant 8.3 month delay and 31% reduction in the risk of disease progression in the liver (hazard ratio 0.69). The clinical benefit of adding SIR-Spheres Y-90 resin microspheres to first-line chemotherapy appears to be independent of the use of bevacizumab,” he stated.

Turning his attention to the side effects seen with the addition of SIR-Spheres Y-90 resin microspheres, Prof. van Hazel stated that, “The clinical benefit we observed was accompanied by an acceptable level of adverse events resulting from the addition of Y-90 resin microspheres to first-line chemotherapy in mCRC. This matters because oncologists familiar with the effects of radiation on healthy liver tissue have traditionally been very cautious of irradiating large liver volumes. SIRFLOX has now shown that we can deliver high doses of radiation to the liver tumours safely, even with the concurrent administration of a potent chemotherapy regimen.”

Summarizing the impact of the new SIRFLOX findings, Prof. van Hazel concluded that, “Even in the absence of a statistically significant improvement in Progression-Free Survival at all sites, as was the case in SIRFLOX, and even as we await overall survival data from the combined 1100-patient SIRFLOX, FOXFIRE and FOXFIRE Global studies in 2017, these new pre-planned sub-group findings for PFS in the liver should lead oncologists to consider adding SIR-Spheres Y-90 resin microspheres to first-line chemotherapy. The liver remains the organ to which colorectal cancer spreads first, and for those patients who are ineligible for potentially curative liver-resection, liver failure due to the growth of liver metastases will unfortunately be the ultimate cause of their death, which makes our findings especially relevant for mCRC patients diagnosed with liver metastases.”

### **About SIR-Spheres Y-90 resin microspheres**

SIR-Spheres Y-90 resin microspheres are a medical device used in an interventional radiology procedure known as selective internal radiation (SIRT), or radioembolisation, which targets high doses of radiation directly to liver tumours. The treatment consists of tens of millions of radioactive Y-90 coated resin particles, each no bigger in diameter than a human hair. Interventional radiologists inject these resin particles, or microspheres, into the hepatic artery via a catheter inserted into the femoral artery through an incision in the groin. The SIR-Spheres Y-90 resin microspheres become lodged in the capillaries that surround liver tumours, where they deliver a high dose of short-range (mean 2.5 mm; maximum 11 mm) beta radiation to the liver tumours, while sparing healthy liver tissue. The low specific gravity of Y-90 resin microspheres allows the blood flow to evenly distribute the radioactivity within and around the liver tumours.

Key SIR-Spheres Y-90 resin microspheres regulatory authorisations include a full PMA Approval from the US FDA, European Union (CE Mark) and Australian TGA Conformity Assessment certification. SIR-Spheres Y-90 resin microspheres 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. SIR-Spheres Y-90 resin microspheres are approved for the treatment of inoperable liver tumours in Australia, the European Union (CE Mark), Argentina (ANMAT), Brazil, and several countries in Asia, such as India and Singapore.

## About Sirtex

Sirtex Medical Limited (ASX:SRX) is an Australian-based global healthcare business working to improve treatment outcomes in people with cancer. Our current lead product is a targeted radiation therapy for liver cancer called SIR-Spheres Y-90 resin microspheres. Approximately 50,000 doses have been supplied to treat patients with liver cancer at more than 800 medical centres in over 40 countries. For more information, please visit [www.sirtex.com](http://www.sirtex.com).

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**Reference:** van Hazel GA *et al.* Presented at the 17<sup>th</sup> World Congress on Gastrointestinal Cancer, 1–4 July 2015, Barcelona, Spain; *Annals of Oncology* 2015; 26 (Suppl 4): Abstract O-019.

**For more information, please contact:**

Kenneth Rabin, PhD [krabin@sirtex-europe.com](mailto:krabin@sirtex-europe.com) +48 502 279 244

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