



**SIR-SPHERES® Y-90 resin microspheres recommended in
new European Society of Medical Oncology (ESMO) Clinical Guidelines
for treating metastatic colorectal cancer (mCRC)**

Bonn, Germany (29th September 2014)

Newly published European Society for Medical Oncology (ESMO) clinical guidelines for the treatment of metastatic colorectal cancer (mCRC) endorse radioembolisation, specifically with Yttrium-90 resin microspheres, as a clinically proven technology to “prolong time to liver tumour progression” in mCRC patients who have failed to respond to available chemotherapy options.

SIR-Spheres Y-90 resin microspheres, the lead product of Sirtex Medical Limited, is the only product used for radioembolisation or Selective Internal Radiation Therapy (SIRT) that is recommended in the new ESMO guidelines.

The new guidelines, authored on behalf of the ESMO Guidelines Working Group by Professors Eric Van Cutsem (Leuven, Belgium), Andres Cervantes (Valencia, Spain), Bernard Nordlinger (Paris, France) and Dirk Arnold (Freiberg, Germany) were published online in a 4 September 2014 supplement to the *Annals of Oncology*.¹

“We are very pleased that the authors of major international clinical guidelines in the treatment of mCRC have singled out radioembolisation, and particularly our unique product, SIR-Spheres Y-90 resin microspheres, as an appropriate treatment for patients with colorectal liver metastases that have failed to respond to chemotherapy,” said Nigel Lange, CEO of Sirtex Medical Europe GmbH. “We believe the new ESMO clinical guidelines will have an immediate effect on improving patient access to SIR-Spheres Y-90 resin microspheres across Europe.”

As clinical evidence for the new ESMO recommendation, the authors cited a multi-centre randomised controlled study conducted by Professor Alain Hendlisz (Brussels, Belgium) and colleagues. The Hendlisz study was a “Phase III trial comparing intravenous fluorouracil infusion with yttrium-90 resin microspheres for liver-limited metastatic colorectal cancer refractory to standard chemotherapy.”²

In April 2013, Sirtex announced that it had completed recruitment of patients for SIRFLOX, a 500-patient randomised clinical study that compares the use of SIR-Spheres Y-90 resin microspheres in combination with standard chemotherapy to standard chemotherapy alone in the treatment of patients recently diagnosed with inoperable mCRC, which is much earlier in the treatment paradigm. Data from SIRFLOX are expected in 2015.

About Metastatic Colorectal Cancer

The new ESMO clinical guidelines state that 447,000 cases of colorectal cancer (CRC) are reported annually in Europe, and 215,000 European patients die from the disease each year. It is the second most-common cancer among both men and women. When CRC spreads, or metastasises, to other parts of the patient's body it becomes mCRC, which is the subject of the new ESMO guidelines.

Of critical importance, one-fourth (25%) of all patients who are newly diagnosed with cancer in their bowels already have mCRC at the time of their diagnosis. One-half (50%) of all colorectal cancer patients will eventually suffer from mCRC. The liver is generally the first and most frequent site of these metastases, which is why the multidisciplinary cancer teams that ESMO recommends to direct the management of mCRC increasingly use combinations of systemic and local treatments, such as liver-directed radioembolisation with SIR-Spheres Y-90 resin microspheres to achieve optimal patient outcomes.

About SIR-Spheres Y-90 Resin Microspheres

SIR-Spheres Y-90 resin microspheres are used to deliver 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 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 microspheres are approved in the European Union (CE Mark) and many other countries for the treatment of liver tumours that are unable to be removed through surgery. Available at more than 700 treatment centres, over 45,000 doses of SIR-Spheres microspheres have been supplied worldwide.

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References

1. Van Cutsem E, Cervantes A, Nordlinger B, Arnold D on behalf of the ESMO Guidelines Working Group. Metastatic colorectal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol* 2014; **25** (Suppl 3): iii1-iii9.
2. Hendlisz A, Van den Eynde M, Peeters M *et al.* Phase III trial comparing protracted intravenous fluorouracil infusion alone or with yttrium-90 resin microspheres radioembolization for liver-limited metastatic colorectal cancer refractory to standard chemotherapy. *J Clin Oncol* 2010; **28**: 3687-3694.

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