

# Leading South African Health Insurer Approves Reimbursement of SIR-Spheres® Y-90 resin microspheres for Patients with Liver Tumours

Bonn, Germany (12 May 2016) – Sirtex (ASX:SRX) announced that Discovery Health, the leading South African private health insurer, has agreed to reimburse SIR-Spheres Y-90 resin microspheres for the treatment of all forms of inoperable liver tumours. SIR-Spheres Y-90 resin microspheres are a medical device used in an interventional radiology procedure known as SIRT or radioembolisation, which targets high doses of radiation directly to liver tumours.

The two most common forms of liver tumours in South Africa today are primary liver cancer (hepatocellular carcinoma or HCC), which is typically caused initially by hepatitis or chronic alcohol use, and liver metastases that have spread from cancer of the bowel (metastatic colorectal cancer or mCRC). According to Globocan data for 2012, the latest year reported, primary liver cancer is the tenth most common form of cancer in South Africa, with 2,000 new cases diagnosed annually. Colorectal cancer is the fifth most frequently diagnosed cancer in South Africa, with 4,700 cases diagnosed. When colorectal cancer spreads, or metastasizes, it most often spreads to the liver. Liver tumours will eventually cause the death of the majority of patients.

Dr Jean-Marc Maurel, Clinical and Radiation Oncologist from GVI Rondebosch Oncology Centre in Cape Town confirmed, "This approval by Discovery Health is good news as it provides improved patient access to SIR-Spheres Y-90 resin microspheres which have been shown in clinical studies to control the growth of liver tumours".

Dr Waldemar Szpak, Radiation Oncologist at Rainbow Oncology Center in Durban, stated "SIRT with SIR-Spheres Y-90 resin microspheres is a technology that allows us to administer high doses of radiation directly to liver tumours without affecting other organs. The large, recent SIRFLOX clinical trial<sup>2</sup> showed that SIRT with SIR-Spheres keeps liver tumours in check for almost eight months longer than regular chemotherapy alone when it was used early in the treatment of patients with metastatic colorectal cancer that had spread only or mainly to the liver. I am pleased that our patients will now have increased access to this technology. This treatment has great potential in the management of other cancers involving liver that are amenable for direct catheterisation and embolisation with SIR-Spheres."

"We are pleased that SIR-Spheres microspheres will now be available to liver cancer patients in South Africa, especially so because South Africa is also my native country. This decision by Discovery Health affirms the strong evidence of efficacy and safety for SIR-Spheres in these patients," said Nigel Lange, Chief Executive Officer of Sirtex Medical for Europe, the Middle East and Africa, whose parent company, Sirtex Medical Limited, developed and continues to study new uses of SIR-Spheres Y-90 resin microspheres in the treatment of liver tumours.

## What is Selective Internal Radiation Therapy (SIRT)?

Selective Internal Radiation Therapy (SIRT) is a non-surgical procedure, in which an interventional radiologist uses a catheter directed through an incision in the patient's femoral artery to deliver a treatment comprising millions of radioactive microspheres (more than 30 million resin microspheres containing radioactive yttrium-90 in the case of SIR-Spheres microspheres) directly into branches of the hepatic (liver) artery. The microspheres are carried by the blood flow through the arteries into the small vessels that nourish tumours in the liver, where they ultimately become trapped due to their size and deliver high doses of beta-radiation directly to the tumours. As internal radiation is delivered directly to tumours, patients can receive radiation doses many times greater than possible with external beam radiation.

### **About SIR-Spheres microspheres:**

SIR-Spheres Y-90 resin microspheres are approved for use in Australia, the United States of America (FDA PMA approval), the European Union (CE Mark), Argentina (ANMAT), Switzerland, Turkey, and several other countries in Asia such as India, and Singapore. Additionally, SIR-Spheres Y-90 resin microspheres are supplied in countries such as Hong Kong, Israel, Malaysia, New Zealand, Taiwan and Thailand. 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 intrahepatic artery chemotherapy using floxuridine. SIR-Spheres Y-90 resin microspheres are indicated for the treatment of inoperable liver tumours in Australia, the European Union, Argentina, 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, SIR-Spheres Y-90 resin microspheres, is a targeted radiation therapy for liver cancer. Approximately 55,000 doses have been supplied to treat patients with liver cancer at more than 900 medical center's in over 40 countries. For more information, please visit www.sirtex.com.

SIR-Spheres<sup>®</sup> is a Registered Trademark of Sirtex SIR-Spheres Pty Ltd.

#### **References:**

- 1. Ferlay J, Soerjomataram I, Ervik M et al. Globocan 2012. v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <a href="http://globocan.iarc.fr">http://globocan.iarc.fr</a>, accessed on 12/May/2016.
- 2. van Hazel GA, Heinemann V, Sharma NK *et al.* SIRFLOX: Randomized Phase III Trial Comparing First-Line mFOLFOX6 (Plus or Minus Bevacizumab) Versus mFOLFOX6 (Plus or Minus Bevacizumab) Plus Selective Internal Radiation Therapy in Patients With Metastatic Colorectal Cancer. *Journal of Clinical Oncology* 2016 Feb 22; ePub doi: 10.1200/JCO.2015.66.1181.

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