SIRTEX MEDICAL LIMITED (ASX: SRX)

An emerging global leader in cancer treatment

Sirtex is a global life-sciences company that develops and delivers oncology treatments using novel small particle technology to help improve outcomes for patients with cancer.

Extending the lives of patients with the use of SIR-Spheres® Y-90 resin microspheres

Sirtex’s principal product is an internal radiation therapy called SIR-Spheres Y-90 resin microspheres which targets high doses of radiation to liver tumors via the hepatic artery. This involves a minimally invasive procedure called Selective Internal Radiation Therapy (SIRT). SIR-Spheres Y-90 resin microspheres are approved in Australia, the European Union (CE Mark), as well as several other countries for the treatment of patients with advanced non-resectable liver tumors. In the USA, SIR-Spheres Y-90 resin microspheres have a full Pre-Market Approval (PMA) from the Food and Drug Administration (FDA) and are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHA) of FUDR (Floxuridine).

SIR-Spheres Y-90 resin microspheres are tiny radioactive resin beads that emit beta radiation and possess unique physical characteristics and biological effects. They are approximately one third the width of a human hair and have about the same specific gravity as a red blood cell. This enables the microspheres to flow with the blood supply and become lodged in the tumor, delivering a high dose of radiation while minimizing the damage to healthy parenchyma.

SIR-Spheres Y-90 resin microspheres are well tolerated and have been demonstrated to be effective in treating non-resectable, metastatic colorectal cancer in patients who have failed prior chemotherapy.

Sirtex in figures

- Sirtex supplies SIR-Spheres Y-90 resin microspheres to more than 40 countries.
- About 1,090 treatment centers around the world use SIR-Spheres Y-90 resin microspheres.
- Over 73,000 patient treatments with SIR-Spheres Y-90 resin microspheres have been supplied.

Innovation through collaboration

Sirtex collaborated with more than 100 world-class universities and research institutions, involving more than 1,000 researchers worldwide to develop new approaches in helping improve the life expectancy of patients with cancer.

Investigating earlier use of SIR-Spheres Y-90 resin microspheres

SIR-Spheres Y-90 resin microspheres are the most widely studied SIRT technology for treating liver tumors. Sirtex invested in a robust clinical trial program of randomized clinical trials. These studies involved more than a hundred leading international medical institutions, a thousand researchers and more than 2,000 patients. These were the largest studies of their kind in the world and they were designed to demonstrate the efficacy and safety of SIR-Spheres Y-90 resin microspheres as a treatment for liver tumors.

The SIRFLOX, FOXFIRE and FOXFIRE Global studies investigated the first-line use of SIR-Spheres Y-90 resin microspheres in combination with the current standard of care chemotherapy, in patients with inoperable tumors in the liver that have spread from the colon. The three studies recruited 1,103 patients to provide sufficient statistical power to examine the survival benefit from the addition of SIR-Spheres Y-90 resin microspheres to current chemotherapy. The survival data from the FOXFIRE Combined Analysis were reported at the May 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO).
Although SIR-Spheres Y-90 resin microspheres in combination with standard first-line mFOLFOX6 chemotherapy did not cause a superior OS in the studied group of patients with liver metastases from colorectal cancer, they did provide a significantly improved median OS by 4.9 months and reduced the risk of death at any given point in time by 36% when given first line in combination with standard mFOLFOX6 chemotherapy for liver-only or liver-dominant mCRC in patients with right-sided primary (RSP) tumors.\(^4\)

The initial results of the SIRFLOX study were presented at the ASCO 2015 Annual Meeting by Professor Peter Gibbs. The final data was published on-line as a Rapid Communication in February 2016 in the *Journal of Clinical Oncology* and the paper was also included in the "Best of JCO: 2016 Annual Meeting Edition".\(^5\) The editors stated that this “paper is required reading and is considered practice-changing”, which suggests that the SIRFLOX regimen could potentially change the treatment journey for patients with mCRC.

The results from this first large-scale, randomized controlled trial of 530 chemotherapy-naive patients with liver-only or liver-dominant mCRC showed that there was no statistically significant improvement in PFS at any site with the addition of SIR-Spheres Y-90 resin microspheres, a finding that was not unexpected with a liver-directed treatment. However, the risk of first progression in the liver as per competing risk analysis remained significantly lower for patients receiving SIR-Spheres Y-90 resin microspheres. The improvement was 7.9 month with an HR of 0.69 corresponding to a 31% reduction in risk of progression in the liver at any point in time.

Sirtex is headquartered in Australia with substantial operations in the US, Singapore and Germany.

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**2017 Full year financial and operating highlights**

- 13 consecutive years of growth
- Record revenues of $234.3 million, up 0.8% on the previous year
- Record dose sales of 12,578, up 5.4% on the previous year
- Net loss after tax of $26.3 million
- Cash balance of $118.3 million, up 10.6% on the previous year and no debt

*Note: All amounts are in Australian Dollars.*

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For more information please visit:

www.sirtex.com

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