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CIRT-EU Registry for SIR-Spheres® Therapy presented at CIRSE 2020 Summit

Largest European-wide observational, multicenter registry of SIR-Spheres Y-90 resin microspheres for liver tumors conducted by CIRSE reports safety and survival data

WOBURN, Mass. (September 15, 2020) — [Sirtex Medical \(“Sirtex”\)](#), a leading manufacturer of targeted liver cancer therapies, announced that new real-life data on safety and overall survival on its lead product, SIR-Spheres® Y-90 resin microspheres, was presented for the first time at the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Virtual 2020 Summit on September 14. With a 1,027-patient cohort in 27 hospitals across eight European countries, CIRT EU is the largest independently conducted European prospective, multicenter observational registry analyzing the treatment of primary and metastatic liver tumors using Y-90 resin microspheres.

The objective of CIRT EU is to assess the clinical application, effectiveness, safety, technical considerations and quality of life of trans-arterial radioembolization (TARE) with Y-90 resin microspheres in real-world clinical practice. Key highlights of the registry include:

- A median overall survival of 16.5 months (95% CI: 14.2-19.3) in 422 patients with hepatocellular carcinoma, 14.7 months (95% CI: 10.9-17.9) in 120 patients with intrahepatic cholangiocellular carcinoma, 9.8 months (95% CI: 8.3-12.9) in 237 patients with metastatic colorectal cancer, and 33.1 months (95% CI: 22.1-nr) in 58 patients with metastatic neuroendocrine tumors.
- Incidence of SAE (Grade 3 or higher) within 30 days of treatment was low (abdominal pain: 2.4%; Fatigue: 1.4%; Radiation cholecystitis: 0.2%, REILD: 0.5%; GI ulceration: 0.4%, Gastritis: 0.3%).

The presentation was led by Professor Thomas Helmberger, Chief of the Institute for Radiology, Neuroradiology and Minimally-Invasive Therapy at München Klinik Bogenhausen in Munich, Germany, and Chairperson of the CIRT Steering Committee.

“I am extremely proud of the CIRSE team for their hard work the last six years to successfully complete this registry,” said Helmberger. “CIRT EU addresses the need for real-life data on Y-90 resin microspheres, and we’re honored to share our findings with the radiology community at CIRSE’s flagship event.”

Researchers confirmed the findings met the primary endpoint of real-life application of TARE using SIR-Spheres across safety, overall survival and prognostic factors. CIRT EU also confirmed effective palliation in hepatic liver metastases from rarer indications, such as neuroendocrine tumors (NET), breast cancer, pancreatic cancer and melanoma.

CIRT EU is the largest observational registry run exclusively by CIRSE and funded by a grant provided by Sirtex Medical Europe.

“We express deep thanks to Professor Helmberger, Professor Ignacio Bilbao and every member of the CIRT EU team for completing this groundbreaking SIR-Spheres registry and advancing the field with important real-world data,” said Dr. Mark Turco, Global Chief Medical Officer and EVP, Research and Development of Sirtex Medical. “We look forward to future data analysis arising from CIRT EU and its positive impact on the treatment of cancer patients in Europe and beyond.”

About Sirtex

Sirtex is a global healthcare business with offices in the U.S., Australia, Europe and Asia, working to improve outcomes in people with cancer. Sirtex’s current lead product is a targeted radiation therapy for liver cancer called SIR-Spheres® Y-90 resin microspheres. More than 100,000 doses have been supplied to treat patients with liver cancer at more than 1,300 medical centers in over 45 countries.

For more information, visit www.sirtex.com.

SIR-Spheres® is a registered trademark of Sirtex SIR-Spheres Pty Ltd.

About SIRT with SIR-Spheres® Y-90 resin microspheres

Selective internal radiation therapy (SIRT) with SIR-Spheres® Y-90 resin microspheres is a prescription device for the treatment of inoperable liver tumours. It is a minimally invasive treatment that delivers high doses of high-energy beta radiation directly to the tumours. SIRT is administered to patients by interventional radiologists, who infuse millions of radioactive resin microspheres (diameter between 20–60 microns) via a catheter into the liver arteries that supply blood to the tumours. By using the tumours’ blood supply, the microspheres selectively target liver tumours with a dose of radiation that is up to 40 times higher than conventional radiotherapy, while sparing healthy tissue.

SIR-Spheres Y-90 resin microspheres are approved for use in Argentina, Australia, Brazil, the European Union (CE Mark), Switzerland, Turkey, and several countries in Asia for the treatment of unresectable liver tumours. In the U.S., SIR-Spheres Y-90 resin microspheres have a Pre-Market Approval (PMA) from the FDA and are indicated for the treatment of unresectable metastatic liver tumours from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (floxuridine).

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