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NASIR-HCC: Phase 2 study of Sirtex Medical SIR-Spheres® Y-90 resin microspheres followed by Nivolumab therapy demonstrates favorable safety and tolerability profile at ILCA 2020

Study results for patients with Hepatocellular Carcinoma presented at International Liver Cancer Association Virtual Conference

WOBURN, Mass. (September 14, 2020) — Sirtex Medical ("Sirtex"), a leading manufacturer of targeted liver cancer therapy, SIR-Spheres® Y-90 resin microspheres, is pleased to report that positive trial data from the NASIR-HCC Study was reported by Professor Bruno Sangro at the International Liver Cancer Association Virtual Conference (ILCA) on September 13, 2020. NASIR-HCC, a multicenter phase 2 single arm clinical trial, evaluated the safety, tolerability, and preliminary antitumoral efficacy of selective internal radiation therapy (SIRT) using Sirtex's lead product SIR-Spheres® Y-90 resin microspheres, followed by Nivolumab, a targeted anti PD-1 cancer therapy manufactured by Bristol Myers Squibb (BMS), in 42 patients with Hepatocellular Carcinoma (HCC).

The Phase 2 study was conducted across nine academic hospitals in Spain. Patients enrolled in NASIR-HCC had large single or multiple tumors including those with unilobar segmental or lobar portal vein thrombosis, preserved liver function, and no extrahepatic disease. Results showed:

- 12% of patients experienced a serious adverse event that were considered related to treatment
- Treatment-related adverse events leading to permanent Nivolumab discontinuation occurred in 2.3% of patients
- Radioembolization-induced liver disease and treatment-related deaths were not observed in this study
- SIR-Spheres® Y-90 resin microspheres followed by Nivolumab demonstrated a favorable safety profile with no signs of synergistic toxicity

While confirmation with future randomized controlled trials is needed to further explore the efficacy of SIRT treatment followed by Nivolumab, overall response rate (ORR) was observed in 40% of patients, including 12.5% and 27.5% who had a complete tumor and partial tumor response, respectively.

The ILCA presentation was led by the NASIR trial principle investigator, Professor Bruno Sangro, Director of the Liver Unit, and Professor of Internal Medicine at the Clinica Universidad de Navarra in Pamplona,

Spain. Professor Sangro received research grants from Sirtex and Bristol Myers Squibb to support the study.

“It’s an honor to present our findings to fellow professionals in the liver cancer community so we can advance oncological care for patients demonstrating safety, tolerability and early antitumoral efficacy of combination therapy with SIRT followed by Nivolumab,” said Professor Sangro. “I express deep thanks to our multicenter team, Sirtex, BMS and our other supporters for their efforts to complete this successful study.”

“We’re excited by the study’s positive safety outcomes and look forward to future trials that will further evaluate treatment with SIR-Spheres® Y-90 resin microspheres in combination with effective PD-1 antagonists like Nivolumab possibly providing improved outcomes for patients with oncologic disease by synergistic activation and priming of immune mediated T-Cells,” said Dr. Mark Turco, Chief Medical Officer & EVP R&D Sirtex Medical. “This trial of world class investigators as well as cross industry collaboration demonstrates a great commitment to advance therapies available to patients with cancer.”

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 tumors. It is a minimally invasive treatment that delivers high doses of high-energy beta radiation directly to the tumors. 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 tumors. By using the tumors’ blood supply, the microspheres selectively target liver tumors 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 tumors. 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 tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (floxuridine).

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