SIRTeX DOORwaY-90 Study

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Sirtex Medical announces new SIR-Spheres® DOORwaY^{90} Study: The first prospective multicenter U.S.-based trial for registration as first-line treatment for hepatocellular carcinoma

WOBURN, Mass. (March 22, 2021) — Sirtex Medical ("Sirtex"), a leading manufacturer of targeted liver cancer therapies, announced full FDA approval of the DOORwaY^{90} Study, a trial evaluating the safety and efficacy of selective internal radiation therapy (SIRT) using SIR-Spheres® Y-90 resin microspheres in patients with unresectable hepatocellular carcinoma (HCC).

Unique to other recently published Y-90 studies, DOORwaY^{90}, which stands for "Duration of Objective Response with Arterial Y-90," is the first prospective, multicenter study to utilize and delineate personalized dosimetry treatment planning and to define actionable post-treatment dosimetric verification for endpoint assessment. The study will assess the duration of response (DoR) and objective response rate (ORR) of SIR-Spheres.

Outside the United States, SIR-Spheres are indicated for the treatment of patients with advanced non-operable liver cancer, including HCC. "Our therapy is used for treatment in HCC in more than 50 countries, with years of safety and efficacy," said Kevin Smith, Chief Executive Officer at Sirtex. "The DOORwaY^{90} Study has the potential to expand the FDA-approved indication for use of SIR-Spheres in the U.S., which would mark an incredible achievement in patient care."

The DOORwaY^{90} Study is being led by co-principal investigators Cheenu Kappadath, PhD, and Dr. Armeen Mahvash. "We are honored to participate in this important study that could greatly impact the treatment of HCC patients in the United States," noted Dr. Mahvash, Professor in the Department of Interventional Radiology Division of Diagnostic Imaging at the University of Texas MD Anderson Cancer Center. "We look forward to working closely with Sirtex in executing and reporting the findings of DOORwaY^{90}."

DOORwaY^{90} is a 15-center, 100-patient, U.S.-based open label, single arm study run in accordance with Good Clinical Practice (cGCP). The study population consists of patients with Barcelona Clinic Liver Cancer (BCLC) Stage A, B1 and B2 who are not eligible for resection or ablation at the time of study entry. For each patient, an eligibility review committee will review diagnostic imaging and confirm final eligibility and treatment planning prior to treatment. Enrollment is expected to begin in early Q2 2021.

HCC is often diagnosed when potentially curative resection or transplantation is not feasible. SIRT has the potential to deliver a lethal dose of radiation to hepatic tumors, while sparing surrounding healthy liver tissue. In countries outside the U.S., SIRT has been successfully used to bridge patients to transplantation or downstage HCC to within transplantation criteria or resection.

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. 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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