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DOORwaY-90 study for SIR-Spheres® therapy as first-line treatment for hepatocellular carcinoma enrolls first patient

First prospective multicenter U.S.-based trial for indication expansion of SIR-Spheres® Y-90 resin microspheres taking place in 15 sites across the U.S.

WOBURN, Mass. (May 10, 2021) — Sirtex Medical ("Sirtex"), a leading manufacturer of targeted liver cancer therapies, announced that the first patient has been enrolled in DOORwaY-90, a study 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).

DOORwaY-90, which stands for "Duration of Objective Response with Arterial Y-90," is the first prospective, U.S.-based multicenter, open-label single arm study of its kind. The study will assess the duration of response (DoR) and objective response rate (ORR) of SIR-Spheres. It is being led by co-principal investigators Cheenu Kappadath, PhD and Dr. Armeen Mahvash. Study enrollment is underway, with the first patient enrolled at Inland Imaging Associates and Providence Sacred Heart Medical Center in Spokane, Washington.

"We are thrilled to enroll the first patient in DOORwaY-90," said Dr. Mark A. Turco, Global Chief Medical Officer and EVP of Research and Development for Sirtex. "This clinical trial studying a heterogeneous population of patients with HCC using personalized dosimetry planning has the potential to advance the treatment of HCC patients worldwide. We are deeply thankful to every clinical investigator and patient who will be part of this groundbreaking journey."

With a planned enrollment of 100 subjects across 15 sites both academic and non-academic, DOORwaY-90 is enrolling 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. The study is unique because it is the first FDA-approved U.S.-based prospective trial to utilize and delineate personalized dosimetry treatment planning and to define actionable post-treatment dosimetric verification for endpoint assessment.

"It's important for physicians to have confidence that their planned Y-90 dose is being delivered in the right amount and to the right place," said Dr. Douglas Murrey, Vascular and Interventional Radiologist at Inland Imaging Associates and Providence Sacred Heart Medical Center in Spokane, Washington. "The personalized dosimetry component of the DOORwaY-90 study will provide meaningful insights to advance our practice and patient outcomes."

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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