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Sirtex Medical's SIR-Spheres® Y-90 Resin Microspheres Receive FDA Approval for the Treatment of Unresectable Hepatocellular Carcinoma

Expanded indication makes SIR-Spheres® the first and only radioembolization therapy in the U.S. approved to treat both unresectable hepatocellular carcinoma and metastatic colorectal cancer

WOBURN, Mass. (July 7, 2025) – Sirtex Medical ("Sirtex"), a leading manufacturer of interventional oncology solutions, today announced that the U.S. Food and Drug Administration (FDA) approved SIR-Spheres® Y-90 resin microspheres for the treatment of unresectable hepatocellular carcinoma (HCC) in the United States. With this approval, SIR-Spheres® is the only radioembolization therapy approved for the treatment of both metastatic colorectal cancer (mCRC) of the liver and HCC in the U.S.

HCC is the most common form of liver cancer in adults in the U.S., according to the American Cancer Society. Radioembolization–commonly referred to as selective internal radiation therapy (SIRT)--with SIR-Spheres® uses personalized dosimetry to deliver the optimal dose of radiation directly to tumors in patients with HCC. This approval gives clinicians expanded flexibility in selecting a liver-directed therapy that aligns with patient-specific needs and treatment goals.

"The expanded indication makes SIR-Spheres® the only Y-90 treatment approved in the U.S. for both HCC and mCRC," said Matt Schmidt, CEO of Sirtex. "This milestone reflects our ongoing commitment to delivering flexible, personalized therapies—with multiple dose options available daily—that empowers physicians to treat patients when and where it works best."

This regulatory milestone is supported by results from the DOORwaY^{90} study, a prospective, multicenter, open-label clinical trial evaluating the safety and efficacy of SIR-Spheres® in treating HCC. The study enrolled 100 patients across 18 U.S. centers, with 65 patients included in the interim primary efficacy cohort. DOORwaY^{90} met its prespecified co-primary endpoints, demonstrating a best overall response rate (ORR) of 98.5% as assessed by independent central review. All evaluable patients demonstrated a response, indicating a 100% local tumor control rate. Additionally, the median duration of response (DoR) exceeded 300 days. These findings highlight SIR-Spheres® as a highly effective liver-directed therapy with a favorable safety profile.

"This study moves the field of radioembolization forward with reproducible dosimetry outcomes and a strong safety profile linked to very positive clinical results," said Dr. Armeen Mahvash, Interventional Radiologist at MD Anderson Cancer Center and Co-Principal Investigator of the DOORwaY^{90} Study. "This will give multidisciplinary care teams the confidence to recommend SIR-Spheres® for HCC treatment."

For more information and details on how to incorporate SIR-Spheres® into your practice, please contact Sirtex at **info-use@sirtex.com**.

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About SIR-Spheres®

SIR-Spheres® Y-90 resin microspheres are indicated for the local tumor control of unresectable hepatocellular carcinoma (HCC) in patients with no macrovascular invasion, Child-Pugh A cirrhosis, well-compensated liver function, and good performance status. They are also indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).

Caution: Federal (USA) law restricts this device for sale by or on the order of a physician. Consult the Instructions for Use (www.sirtex.com/sir-spheres/risks_adverse-events) for a complete listing of indications, contraindications, side effects, warnings and precautions.

About Sirtex

Sirtex Medical is a global healthcare company focused on advancing minimally invasive, liver-directed cancer and embolization therapies. With offices in the U.S., Australia, Europe, and Asia, Sirtex delivers innovative interventional oncology and embolization solutions to physicians and patients worldwide. The company's lead product, SIR-Spheres® Y-90 resin microspheres, is now the only FDA approved product in the United States indicated for both the treatment of hepatocellular carcinoma (HCC) and metastatic colorectal cancer (mCRC). For more information, visit www.sirtex.com.

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