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Sirtex Medical's DOORwaY^{90} Study Demonstrates 100% Local Tumor Control with SIR-Spheres®, Setting a New Benchmark in Y-90 for HCC

The DOORwaY^{90} study met its prespecified co-primary endpoints, achieving a best overall response rate (ORR) of 99%

WOBURN, Mass. (April 13, 2026) – Sirtex Medical ("Sirtex"), a leading manufacturer of interventional oncology and embolization solutions, today announced landmark 12-month results from the DOORwaY^{90} study, the first pivotal, prospective, multicenter U.S. trial of Y-90 selective internal radiation therapy (SIRT) using partition dosimetry in patients with unresectable hepatocellular carcinoma (HCC).

The DOORwaY^{90} study met its prespecified co-primary endpoints, demonstrating a 90% complete response (CR) rate and a best overall response rate (ORR) of 99%, as assessed by blinded independent central review. All evaluable patients responded to treatment, resulting in 100% local tumor control—one of the highest reported response outcomes in Y-90 therapy. Responses were durable, with 75% lasting beyond six months and a median duration of 295 days, reinforcing the potential of SIR-Spheres Y-90 resin microspheres to deliver sustained tumor responses while preserving liver function.

Importantly, over 95% of patients maintained stable liver function at 12 months, underscoring the ability of personalized dosimetry to achieve aggressive tumor response without compromising hepatic reserve.

These results were presented as a late-breaking oral presentation at the Society of Interventional Radiology (SIR) Annual Meeting in Toronto, Canada.

"These 12-month results demonstrate the consistency of response achievable with personalized dosimetry," said Dr. Armeen Mahvash, Interventional Radiologist at MD Anderson Cancer Center and Co-Principal Investigator of the DOORwaY^{90} study. "The high complete response rates, durability and preservation of liver function observed in this study give physicians increased confidence in using radioembolization as a definitive, liver-directed treatment option."

"These results raise the bar for what physicians should expect from Y-90 therapy," said Matt Schmidt, CEO of Sirtex Medical. "With the overall response rate of 99% and 100% tumor control, DOORwaY^{90} demonstrates that personalized dosimetry with SIR-Spheres can deliver outcomes that challenge conventional approaches and expand what's possible in liver-directed therapy for patients with unresectable HCC."

SIR-Spheres Y-90 resin microspheres are the only radioembolization therapy approved by the FDA for the treatment of both metastatic colorectal cancer (mCRC) of the liver and unresectable HCC in the U.S.

For more information about SIR-Spheres and guidance on incorporating personalized dosimetry into clinical 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. Common side effects include abdominal pain, nausea and constipation. Consult www.sirtex.com/sir-spheres/risks_adverse-events for a complete listing of side effects, warnings and precautions.

About Sirtex
Sirtex Medical is a global healthcare company focused on advancing minimally invasive cancer and embolization therapies. With offices in the U.S., Australia, Europe, and Asia, Sirtex delivers innovative minimally invasive interventional oncology and embolization solutions to physicians and patients worldwide. For more information, visit www.sirtex.com.

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