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Sirtex Medical secures positive approval of SIR-Spheres® Y-90 resin microspheres for HCC treatment in Brazil

The Brazilian National Agency of Supplementary Health recommends SIR-Spheres for the treatment of intermediate- and advanced-stage hepatocellular carcinoma

WOBURN, Mass. (September 15, 2022) – [Sirtex Medical \(“Sirtex”\)](#), a leading manufacturer of targeted liver cancer therapies, announced that the Brazilian National Agency of Supplementary Health (ANS) approved SIR-Spheres® Y-90 resin microspheres for the treatment of intermediate and advanced stage hepatocellular carcinoma (HCC) in Brazil.

In an update to its List of Health Procedures and Events, ANS recommends SIR-Spheres for use in selective internal radiation therapy (SIRT), a minimally invasive treatment that delivers high doses of radiation directly to tumors while sparing surrounding healthy liver tissue. Sirtex received product approval from the Brazilian Health Regulatory Agency (ANVISA) for SIR-Spheres in 2014.

“This milestone represents the close collaboration we have fostered with Brazilian colleagues, interventional radiologists and respected regulatory entities like ANS over the last six years,” said Kevin R. Smith, Chief Executive Officer of Sirtex. “We celebrate the recognition of SIR-Spheres to advance care for HCC patients, and we also reaffirm our commitment to global growth and partnership for more effective cancer treatment worldwide.”

The proposals for incorporation into the ANS List of Health Procedures and Events underwent broad social participation and careful technical analysis by the ANS, using the methodology of health technology assessment, similar to England, Canada, Australia and Germany. In Brazil, liver cancer has the 11th-highest cancer incidence, representing 2.1% of new cases and 4.7% of total cancer-related deaths, which highlights the burden and severity of this disease.

“The ANS recommendation of SIR-Spheres solidifies it as a valuable treatment option, especially since 76% of HCC patients in Brazil are diagnosed at an advanced stage when treatments of curative intent are no longer an option¹,” said Dr. Joaquim Maurício da Motta Leal Filho, President of the Brazilian Society of Interventional Radiology and Endovascular Surgery (SOBRICE). “As we continuously strive to improve outcomes for patients, we are proud of this achievement and feel gratitude to the many people who contributed to this decision.”

In addition to Brazil, SIR-Spheres are approved for use in Argentina, Australia, 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).

1 Fernandes GDS et al. Epidemiological and Clinical Patterns of Newly Diagnosed Hepatocellular Carcinoma in Brazil: the Need for Liver Disease Screening Programs Based on Real-World Data. J Gastrointest Cancer. 2021 Sep;52(3):952-958. doi: 10.1007/s12029-020-00508-7. Erratum in: J Gastrointest Cancer. 2020 Oct 26;: PMID: 32918274; PMCID: PMC8376733.

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.

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