NCCN Guidelines® Recommend SIR-Spheres® Y-90 Resin Microspheres for the Treatment of Metastatic Colorectal Cancer

Expert panel reaches uniform consensus that yttrium-90 microspheres is an appropriate option for patients with colorectal liver metastases

WOBURN, Mass.--Sirtex Medical Limited (ASX: SRX) today announced that SIR-Spheres® Y-90 resin microspheres has been included as a Category 2A recommended treatment in the latest National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology for colon cancer and rectal cancer. This designation denotes that there is uniform consensus among the NCCN panel that Selective Internal Radiation Therapy (SIRT) with yttrium-90 microspheres is an appropriate option in patients with liver dominant, chemotherapy resistant colorectal disease (mCRC). This recommendation places SIR-Spheres Y-90 resin microspheres at the same designation as the recommended mCRC systemic chemotherapeutic regimens.

The new NCCN Guidelines are available online at https://www.nccn.org/professionals/physician_gls/f_guidelines.asp

Nearly 140,000 Americans are diagnosed with colorectal cancer every year[1], more than 50 percent of whom will see the cancer spread to their liver.[2] "The NCCN Guidelines aim to assist medical teams, patients and their families in making informed treatment-related decisions with the goal of optimal cancer care," said Kevin Richardson, chief executive officer for Sirtex Americas. "The 2A designation represents a very important milestone for SIR-Spheres resin microspheres and provides further validation for the role of our medical device as an important treatment option for unresectable, liver dominant metastatic colorectal cancer. We also have positive signals in the first-line setting through the results to date of the pivotal SIRFLOX study[3] and eagerly anticipate the overall survival results in more than 1,100 patients from the SIRFLOX, FOXFIRE and FOXFIRE Global studies which we expect to be available in the first half of 2017."

These findings are also supported by the landmark MORE study[4], a large retrospective analysis conducted in the United States with SIR-Spheres Y-90 resin microspheres in more than 600 mCRC patients. The MORE study helped to increase the understanding of SIRT as a treatment option for patients who have failed multiple lines of chemotherapy while highlighting the positive aspects of the safety and efficacy of the protocol for patients of all ages.

"Clinical research has shown that SIRT brings patients with colorectal liver metastases improved and prolonged quality of life," said lead investigator of the MORE study, Andrew S. Kennedy, M.D., F.A.C.R.O., director, Radiation Oncology Research at Sarah Cannon Research Institute, Nashville, Tenn. "We look forward to expanding access to this outpatient procedure, which has demonstrated minimal side effects, to improve outcomes for this population of patients and advance the standard of care."

SIR-Spheres Y-90 resin microspheres are the first and only microspheres with FDA premarket approval (PMA) for colorectal cancer that has metastasized to the liver.[5]

About Selective Internal Radiation Therapy using SIR-Spheres® Y-90 resin microspheres

SIR-Spheres® Y-90 resin microspheres are a medical device used in an interventional radiology procedure known as selective internal radiation therapy (SIRT), or radioembolization, which targets high doses of radiation directly to liver tumors. The treatment consists of tens of millions of radioactive Y-90 coated resin particles, each no bigger in diameter than a human hair. Interventional radiologists inject these resin particles, or microspheres, into the hepatic artery via a catheter inserted into the femoral artery through an incision in the groin. The Y-90 resin microspheres become lodged in the capillaries that surround liver tumors, where they deliver a high dose of short-range (mean 2.5 mm; maximum 11 mm) beta radiation to the liver tumors, while sparing healthy liver tissue. The low specific gravity of the Y-90 resin microspheres allows the blood flow to distribute the radioactivity within and around the liver tumors.

Available at more than 550 treatment centers in the U.S., more than 67,000 doses of SIR-Spheres Y-90 resin microspheres have been supplied worldwide.

SIR-Spheres Y-90 resin microspheres have a Premarket Approval (PMA) by the FDA and are indicated for the treatment of non-resectable metastatic liver tumors from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using floxuridine. SIR-Spheres Y-90 resin microspheres are approved for the treatment of inoperable liver tumors in Australia, the European Union, Argentina, Brazil, Canada and several countries in Asia, such as India and Singapore.

About the National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®), a not-for-profit alliance of 27 of the world's leading cancer centers devoted to patient care, research, and education, is dedicated to improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. As the arbiter of high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers.

About Sirtex

Sirtex Medical Limited (ASX:SRX) is an Australian-based global healthcare business working to improve outcomes in people with cancer. Our current lead product is a targeted radiation therapy for liver cancer called SIR-Spheres Y-90 resin microspheres. More than 67,000 doses have been supplied to treat patients with liver cancer at more than 1,000 medical centers in over 40 countries.

For more information, visit www.sirtex.com.

About Sarah Cannon Research Institute

Sarah Cannon Research Institute is the research arm of Hospital Corporation of America's global cancer institute, Sarah Cannon. Focused on advancing therapies for patients, it is one of the world's leading clinical research organizations conducting community-based clinical trials throughout the United States and United Kingdom. Sarah Cannon's network of strategic sites includes more than 275 physicians who engage in research. The organization has led more than 250 first-in-man clinical trials since its inception in 1993, and has been a clinical trial leader in more than two-thirds of approved cancer therapies over the last 10 years. Additionally, Sarah Cannon offers management, regulatory, and other research support services for drug development and industry sponsors as well as strategic investigator sites through its contract research organization (CRO), Sarah Cannon Development Innovations (formerly known as SCRI Development Innovations). For more information, visit sarahcannon.com.

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References

1. American Cancer Society. *Colorectal Cancer Facts & Figures 2014-2016.* Atlanta: American Cancer Society, 2014. Available at: http://www.cancer.org/acs/groups/content/documents/document/acspc-042280.pdf. Assessed on December 8, 2016.
2. **Cho M, Gong J and Fakih M**. The state of regional therapy in the management of metastatic colorectal cancer to the liver. *Expert Review of Anticancer Therapy*, 2016; 16 (2): 229–245.
3. **van Hazel GA, Heinemann V, Sharma NK et al.** SIRFLOX: Randomized Phase III trial comparing first-line mFOLFOX6 (plus or minus bevacizumab) plus selective internal radiation therapy in patients with metastatic colorectal cancer. *Journal of Clinical Oncology*. 2016; 34: 1723–1731.
4. **Kennedy AS, Ball D, Cohen SJ et al.** Multicenter evaluation of the safety and efficacy of radioembolization in patients with unresectable colorectal liver metastases selected as candidates for 90Y resin microspheres. *Journal of Gastrointestinal Oncology*. 2015; 6: 134–142.
5. *SIR-Spheres® microspheres* (Yttrium-90 Microspheres) Product Information.Available at: www.sirtex.com/us/clinicians/package-insert/. Assessed on December 8, 2016.

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