



Treatment Results of SIR-Spheres® Y-90 Resin Microspheres are Similar Regardless of Patient Age, New Publication Shows

606-patient MORE Study Sub-Group Analysis Examined Outcomes for Elderly (≥ 70 years) and Very Elderly (≥ 75 years) Patients with Liver-Dominant Metastatic Colorectal Cancer (mCRC)

Sydney, Australia (19 January 2016) – A new analysis of the MORE data on 606 mCRC patients treated with SIR-Spheres Y-90 resin microspheres at 11 U.S. medical centres, published late last year in the journal *Clinical Colorectal Cancer*, confirms that patient age is not a barrier to appropriate treatment with SIR-Spheres® Y-90 resin microspheres, Sirtex reported today.

“The analysis of the data from the MORE study confirmed that age alone should not exclude patients from being considered for, or receiving, SIR-Spheres® Y-90 resin microspheres treatment,” said principal study author, Andrew S. Kennedy, MD, Director, Radiation Oncology Research, Sarah Cannon Research Institute. “Because older mCRC patients tend to receive less intense systemic therapy, local liver tumour control with selective internal radiation therapy, or radioembolisation, may provide added benefits to this population. We look forward to continuing our research in this field to determine the most effective treatments for this patient population and improve outcomes.”

The new MORE analysis divided the 606-patient population into two groups, 446 patients under age 70 years at the time of treatment and 160 patients age 70 years or older when treated. Researchers also separately analysed the data for 90 very elderly patients who were age 75 and above. Mean ages in the younger, elderly, and very elderly groups were 55.9 ± 9.4 years, 77.2 ± 4.8 years, and 80.2 ± 3.8 years, respectively. The researchers found that regardless of their age, the patients tended to have similar baseline characteristics.

However, the elderly patients were more likely ($P < 0.001$) to have liver metastases that did not occur at the same time as their primary tumour (metachronous tumours) or to have undergone previous surgery for their primary tumour ($P = 0.009$). Elderly patients also tended to have received fewer lines of chemotherapy treatment ($P = 0.036$) or no previous chemotherapy ($P < 0.001$) at all and were likely to have experienced a longer period of time between diagnosis and radioembolisation ($P = 0.011$). In addition, the older patients were less likely to have received more than one radioembolisation procedure.

Overall survival was statistically the same ($P = 0.335$) between the older (9.3 months) and younger patients (9.7 months). There were also no age-related differences for any grade of adverse event ($P = 0.433$), including the more serious or grade 3+ events ($P = 0.482$) within 90 days of treatment. Of note, gastrointestinal side-effects were reported less frequently in elderly patients than in younger ones.

Similar profiles were also observed in comparisons between patients 75 years and older and those who were younger than 75 years old. Median overall survival was 9.3 months compared to 9.6 months ($P = 0.987$), respectively, and there were no significant differences in either grade 3+ adverse events ($P = 0.398$) or any adverse event ($P = 0.158$) within 90 days of treatment.

About 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 (SIRT), or radioembolisation, which targets high doses of radiation directly to liver tumours. 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 SIR-Spheres Y-90 resin microspheres become lodged in the capillaries that surround liver tumours, where they deliver a high dose of short-range (mean 2.5 mm; maximum 11 mm) beta radiation to the liver tumours, while sparing healthy liver tissue. The low specific gravity of Y-90 resin microspheres allows the blood flow to evenly distribute the radioactivity within and around the liver tumours.

SIR-Spheres microspheres are approved for use in Australia, the United States of America (FDA PMA approval), the European Union (CE Mark), Argentina (ANMAT), Switzerland, Turkey, and several other countries in Asia such as India, Singapore, and Hong Kong. Additionally, SIR-Spheres microspheres are supplied in countries such as New Zealand, Malaysia, Thailand, Taiwan, and Israel.

SIR-Spheres Y-90 resin microspheres are indicated in the United States for the treatment of non-resectable metastatic liver tumours from primary colorectal cancer in combination with intra-hepatic artery chemotherapy using floxuridine. SIR-Spheres Y-90 resin microspheres are indicated for the treatment of inoperable liver tumours in Australia, the European Union, Argentina, Brazil, and several countries in Asia, such as India and Singapore.

About Sirtex

Sirtex Medical Limited (ASX: SRX) is an Australian-based global healthcare business working to improve treatment outcomes in people with cancer. Our current lead product is a targeted radiation therapy for liver cancer called SIR-Spheres Y-90 resin microspheres. Approximately 55,000 doses have been supplied to treat patients with liver cancer at more than 900 medical centres in over 30 countries. For more information, please visit www.sirtex.com.

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About Sarah Cannon Research Institute

Sarah Cannon Research Institute is the research arm of HCA'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 through affiliations with a network of more than 1,000 physicians across the United States and United Kingdom. Sarah Cannon has led approximately 200 first-in-human clinical trials since its inception in 1993, and has been a clinical trial leader in nearly 80 percent of approved cancer therapies in 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. For more information, visit sarahcannon.com.

Reference: Kennedy AS, Ball DS, Cohen SJ *et al.* Safety and efficacy of radioembolization in elderly (≥ 70 years) and younger patients with unresectable liver-dominant colorectal cancer. *Clinical Colorectal Cancer* 2015 Nov 2; ePub doi: 10.1016/j.clcc.2015.09.001.

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