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Press Release

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SIR-Spheres[®] microspheres as Effective and Safe in the Elderly as they are in Younger Patients with Colorectal Liver Metastases According to Data Released at ASCO Annual Meeting

Landmark analysis provides key insights into treatment pathways for patients aged 70 and older

CHICAGO (May 30, 2013) — Results from the first, large multi-center study evaluating Selective Internal Radiation Therapy (SIRT) with SIR-Spheres[®] microspheres in patients ages 70 years and older were released today at the American Society of Clinical Oncology (ASCO) Annual Meeting. According to investigators, the use of SIR-Spheres microspheres in elderly patients with unresectable colorectal liver metastases (mCRC) appears to be as effective and well-tolerated as in younger patients.¹ The findings were released by lead investigator of the MORE study, Andrew S. Kennedy, M.D., F.A.C.R.O., Director, Radiation Oncology Research at the Sarah Cannon Research Institute, Nashville, Tenn.

“Many standard chemotherapy regimens are either not offered to elderly patients or are given at lower, potentially less effective levels due to the perception or existence of data indicating that elderly patients cannot tolerate these drugs,” noted Dr. Kennedy. “As a result, this population of patients has been left without effective treatment options.”

Due to the minimally invasive nature of Y-90 microsphere therapy, Dr. Kennedy and researchers hypothesized that SIRT may provide an effective treatment option for older patients without the concerns of side effects often seen with chemotherapy.

“The outcomes of this study are significant since the oncology community has long struggled to understand the best approach for treating older patients with inoperable liver tumors,” added Kennedy. “The fact that we were able to show in this study that out-patient treatment sessions with SIRT are equally as effective in elderly patients compared to those who are younger is an important development. However, the real key takeaway is that SIRT was just as well-tolerated in patients ages 70 and older. Too many times we undertreat this patient population or they themselves choose to forgo treatment due to concerns about quality of life.”

Part of the landmark MORE study, this retrospective analysis evaluated clinical outcomes among 160 elderly (≥ 70 years) and 446 younger (< 70 years) patients with unresectable mCRC consecutively treated using SIR-Spheres microspheres from July 2002 to December 2011 at 11 U.S. institutions. Regardless of age, patients were similar in terms of sex, race, performance status and other characteristics.

Outcomes between both cohorts were similar following treatment with SIR-Spheres microspheres. Median overall survival in elderly patients was 9.3 months compared to 9.7 in the

younger group. The treatment was equally well-tolerated in both age groups, with no significant increase in grade 3+ adverse events in elderly patients. The most common grade 3+ events were abdominal pain and fatigue. Investigators also noted that a sub-analysis of the oldest patients in the study (98 patients ≥ 75 years) compared to younger patients also confirmed equivalent outcomes for survival and toxicity.

“People are not only living longer, but they are living longer with a better quality of life. To offer an outpatient procedure with minimal side effects compared to potentially toxic chemotherapy options is a tremendous benefit,” said Mike Mangano, President of Sirtex Medical Inc. “This study shows that there is an equal opportunity to improve survival time and quality of life in this group of patients. Our goal is to use these findings to help generate meaningful conversations among the oncology community, elderly patients and caregivers to help make the best decisions regarding treatment.”

Media Note

Dr. Kennedy is available at ASCO for media interviews. Additionally, Mike Mangano, President of Sirtex Medical Inc., can speak to the implications of the study. To schedule a briefing please contact Elizabeth Romero at elizabeth.romero@fleishman.com.

¹ Kennedy AS, Ball D, Steven J. Cohen SJ et al. Safety and efficacy of resin ⁹⁰Y-microspheres in elderly (≥ 70 years) compared to younger patients with colorectal liver metastases (mCRC). ASCO 2013; Abs. #e14545.

About Selective Internal Radiation Therapy using SIR-Spheres microspheres

Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a proven technology for inoperable liver cancer that delivers doses of radiation directly to the site of tumors. In a minimally invasive treatment, millions of radioactive SIR-Spheres microspheres are infused via a catheter into the liver where they selectively target liver tumors with a dose of internal radiation up to 40 times higher than conventional radiotherapy, while sparing healthy tissue.

Clinical studies have confirmed that patients with metastatic colorectal cancer treated with SIR-Spheres microspheres have response rates higher than with other forms of treatment, resulting in increased life expectancy, greater periods without tumor activity and improved quality of life. SIRT has been found to shrink liver tumors more than chemotherapy alone.

SIR-Spheres microspheres are approved for use in Australia, the United States of America (FDA PMA approval), the European Union (CE Mark) and Argentina (ANMAT). Additionally, SIR-Spheres microspheres are supplied in countries such as Hong Kong, Malaysia, Singapore, Thailand, Taiwan, India, Israel, and Turkey. Available at more than 600 treatment centers, over 34,000 doses of SIR-Spheres microspheres have been supplied worldwide.

For more information, visit www.sirtex.com.

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