



Press Release

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Data Presented at ASCO-GI Symposium Provides New Insights into Predicting SIR-Spheres[®] microspheres Treatment Outcomes

Researchers point to the role of pre-treatment laboratory tests and new modeling technology for enhancing delivery of treatment

SAN FRANCISCO (JANUARY 16, 2014) — Investigators from the landmark MORE (Metastatic colorectal cancer liver metastases Outcomes after Radio Embolization) study today released new findings at the American Society of Clinical Oncology's 2014 Gastrointestinal Cancers Symposium confirming that standard laboratory tests are a valuable tool for predicting patient outcomes prior to Selective Internal Radiation Therapy (SIRT).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.

The MORE data demonstrates that diagnostic results showing organ function and biochemical blood levels offer insights into correctable levels to improve the patient's response to SIRT.

To complement these data, Dr. Kennedy also presented a proposed method that enables complex modeling of the hepatic arterial route and the tumor microvascular bed in which the ⁹⁰Y-microsphere radioactive particles will become permanently embedded. This shows promise to more accurately outline the path microspheres take to the tumor arteriole end which may improve treatment success.²

"Together, these findings provide valuable insights about the enhanced degree of precision that we can achieve as we seek to further improve patient outcomes using SIR-Spheres[®] microspheres," said Dr. Kennedy.

Retrospective Analysis of Standard Laboratory Tests (Abstract #292)

"The MORE study, which began in 2002, is comprised of data from 606 mCRC patients at 11 US institutions making it among the largest of all radioembolization studies," said Dr. Kennedy. "The study's size and consistent results have allowed us to address one of the most common problems faced by the oncology community – once an mCRC patient has failed multiple lines of chemotherapy there is no standard of care to battle the disease. These compelling results have increased understanding of SIRT as a treatment option for this unique patient population while highlighting the positive aspects of the safety and efficacy."

Among the data collected in the retrospective review of MORE, were values for the following parameters 10 days prior to treatment: hemoglobin, albumin, alkaline phosphatase, AST, ALT, total bilirubin and creatinine. CTCAE grades were assigned to each parameter and analyzed for impact on survival by line of chemotherapy. Where applicable, Consensus Guidelines were used to establish the abnormal limits for SIRT.

The 606 patients were studied with a median follow-up of 8.5 months after SIRT. Fewer than 11% of patients were treated outside recommended guidelines, with grade 2 albumin being the most common at time of SIRT. Abnormal parameters were associated with statistically significantly decreased median survivals.

“The MORE team concluded that review of pre-SIRT laboratory parameters may aid in improving median survivals if abnormal values can be addressed prior to radiation delivery,” continued Dr. Kennedy. “These efforts are important in optimizing treatment response to liver radiotherapy.”

Predictive Modeling of the Hepatic Arterial Tree and Tumor Microvasculature (Abstract #248)

Aimed at further advancing the SIRT treatment approach, fractal methods were used to develop a software tool representing the microvasculature of the human liver and different organs and can account for disease states such as liver tumors. Normal liver and tumor artery trees were created, with malignant vessels employing a random generator at each node resulting in corkscrew, bifurcation and/or trifurcation daughter vessel pattern.

The team concluded that predictive modeling may now be possible for microspheres exiting from a catheter into the hepatic artery to its final position in a tumor end arteriole, or for systemic therapies.

“The findings presented by Dr. Kennedy and his respective teams share the common theme of improving SIRT patient outcomes, an area that we are fully dedicated to,” said Mike Mangano, president of Sirtex Medical Inc. “We are fortunate to have so much insightful research to draw upon in the area of microsphere delivery. The data presented at ASCO-GI emphasize a personalized approach to treatment and the medical team’s ability to map the delivery in order to predict the most accurate results for an individual.”

Media Note

Dr. Kennedy is available at ASCO-GI 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.

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), Argentina (ANMAT), New Zealand, Switzerland, Turkey, and several other countries in Asia such as India, Korea, Singapore, and Taiwan. Additionally, SIR-Spheres microspheres are supplied in countries such as Malaysia,

Thailand, Hong Kong, and Israel. Available at more than 700 treatment centers, over 35,000 doses of SIR-Spheres microspheres have been supplied worldwide.

For more information, visit www.sirtex.com.

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¹ Kennedy, A.S., Ball, D., Cohen, S.J., Cohn, M., Coldwell, D.M., Drooz, A., Wang, E. Pre-⁹⁰Y hepatic radiotherapy hemoglobin and liver functions predict overall survival in unresectable chemotherapy refractory metastatic colorectal cancer. *ASCO Gastrointestinal Cancers Symposium 2014*; Abs. 292.

² Kennedy, A., Clipp, R., & Christensen, D. First in man fractal methodology to model both the hepatic arterial tree and tumor microvasculature for ⁹⁰y-microsphere brachytherapy. *ASCO Gastrointestinal Cancers Symposium 2014*; Abs. 248.