Large U.S. Multi-Center Study Confirms Safety and Efficacy of SIR-Spheres@ microspheres in More Than 600 Patients with Unresectable Liver Metastases

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CHICAGO--(BUSINESS WIRE)--Jun 4, 2012-- SIR-Spheres(R) microspheres are well-tolerated and effective internal radiotherapy for unresectable, heavily pre-treated colorectal cancer liver metastases, according to results from a new study of more than 600 patients presented today at the 2012 American Society of Clinical Oncology (ASCO) Annual Meeting. The data were presented by lead investigator Andrew Kennedy, M.D., FACRO, from Cancer Centers of North Carolina and North Carolina State University.1 SIR-Spheres microspheres are manufactured by Sirtex and are the only fully FDA-approved microsphere radiation therapy for the treatment of colorectal liver metastases.

"This is the largest, most comprehensive study to date evaluating the use of Selective Internal Radiation Therapy (SIRT) in liver metastases from colorectal cancer," said Dr. Kennedy. "The data presented at ASCO confirm the safety and efficacy of this treatment option for patients and provide truly useful, validated information for clinicians. It is our hope that these results will help encourage appropriate patient selection discussion during tumor boards and with individual patients and their families." SIR-Spheres microspheres are a novel outpatient treatment for colorectal liver metastases, both alone and in combination with chemotherapy. SIR-Spheres microspheres were FDA approved for use in colorectal liver metastases in 2002 and are now available at more than 400 cancer centers worldwide.

Multi-Institutional U.S. Study Overview The investigator-initiated retrospective study presented at ASCO analyzed the outcomes of using SIR-Spheres microspheres in U.S.

patients treated since 2002. The study's endpoints included safety and tolerability, tumor response and survival.

The study focused on 606 patients (233 women; 373 men) at 10 institutions, who received a total of 966 SIRT treatments. Their mean age was 61.5 years (range, 20.8 to 91.9 years). Active extra-hepatic disease was present prior to the first SIRT procedure in 35.1% of patients. The vast majority (at least 92.6 of patients had received prior chemotherapy, with over 30% having also received prior liver surgery or ablation.

The median overall survival for these heavily pre-treated patients was 9.6 months (95% CI 9.0-11.1) from their first SIRT treatment, with a median follow-up of 8.6

months (0.1-77.7 months). Reported adverse events were typically transient in duration and mild or moderate in severity. In total, 45% of patients had fatigue, 28% experienced nausea and 1% had liver failure. Only 2.1% of all treatments required an overnight stay following the procedure.

The modern U.S. experience of SIRT using SIR-Spheres microspheres for unresectable, heavily pre-treated colorectal liver metastases confirms recently published data from international studies by Hendlisz, Seidensticker and Bester, who independently reported median overall survivals of 10.0, 8.3 and 11.9 months, respectively, in similar cohorts of patients with chemotherapy refractory disease.2-4 "The results of this study, collected from experienced treatment sites across the U.S., are further evidence of the safety and efficacy of SIR-Spheres microspheres in heavily pre-treated patients," said Mike Mangano, president of Sirtex Medical Inc. "This also highlights that SIR-Spheres microspheres provide clear survival benefits with limited toxicity in a patient population with few treatment options." About Selective Internal Radiation Therapy using SIR-Spheres microspheres Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a novel 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 approval), and the European Union (CE Mark) and additionally supplied in countries such as Hong Kong, Malaysia, Singapore, Thailand, Taiwan, India, Israel and Turkey. Available at more than 400 treatment centers, over 20,000 doses of SIR-Spheres microspheres have been administered worldwide.

For more information, visit www.sirtex.com.

SIR-Spheres(R) is a registered trademark of Sirtex SIR-Spheres Pty Ltd References -- Kennedy AS, Ball D, Cohen SJ et al. USA patients receiving resin 90Y microspheres for unresectable colorectal liver metastases: A multi-center study of 506 patients. ASCO Annual Meeting 2012,Journal of Clinical Oncology 2012; 30 (suppl): Abs. 3590. (updated results, as presented) -- Hendlisz A, Van den Eynde M, Peeters M et al. Phase III trial comparing protracted intravenous fluorouracil infusion alone or with yttrium-90 resin microspheres radioembolization for liver-limited metastatic colorectal cancer refractory to standard chemotherapy.

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CONTACT: Fleishman-Hillard on behalf of Sirtex Medical Kassidie Blackstock, 919-457-0749 Kassidie.Blackstock@fleishman.com KEYWORD: UNITED STATES NORTH AMERICA ILLINOIS INDUSTRY KEYWORD: HEALTH CLINICAL TRIALS ONCOLOGY RADIOLOGY RESEARCH SCIENCE SOURCE: Sirtex Medical Copyright Business Wire 2012 PUB: 06/04/2012 09:00 AM/DISC: 06/04/2012 09:00 AM
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