

## **Journal of Clinical Oncology Publishes Study of Colorectal Liver Metastases Patients Treated with Combination Radiofrequency Ablation and Chemotherapy Suggesting Survival Benefit**

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)--April 1, 2005--

Cleveland Clinic Researchers Demonstrate Median Survival of 28.9 Months for Patients Treated with a Combination of Radiofrequency Ablation and Chemotherapy

RITA Medical Systems, Inc. (Nasdaq:RITA) today announced that an article published in the March 1, 2005 (Volume 23, Number 7) issue of the Journal of Clinical Oncology (JCO) reported long-term survival rates for 135 patients treated with radiofrequency ablation (RFA) for hepatic colorectal metastases at The Cleveland Clinic in Cleveland, Ohio. The study enrolled people with metastatic colorectal cancer that had progressed despite prior chemotherapy treatment. Authors of the JCO article, "Predictors of Survival After Radiofrequency Thermal Ablation of Colorectal Cancer Metastases to the Liver: A Prospective Study," concluded that the results of the study suggest the addition of RFA to modern chemotherapy provides "a survival advantage when compared to chemotherapy alone."

"We believe the clinical data demonstrate that a wider range of patients with inoperable colorectal liver metastases may benefit from RFA than previously thought," said Allan Siperstein, MD, a physician in the Department of General Surgery at The Cleveland Clinic and the study's senior author. "The data support the use of radiofrequency ablation even in patients who have cancer outside the liver, or other risk factors from complications associated with their cancer."

The article follows 135 consecutive patients who had colorectal liver metastases, all of whom were not considered candidates for surgical resection, as judged by an interdisciplinary team of hepatobiliary surgeons, interventional radiologists and medical oncologists. Eighty percent of the treated patients had previously undergone and failed chemotherapy treatment, demonstrated by intrahepatic tumor progression. Fourteen percent of the patients (nineteen patients) had previous liver resection, and thirty percent of the patients (forty patients) had extrahepatic disease (cancer outside of the liver). Patients in the study continued to receive second-line chemotherapy after RFA when indicated. The median survival (Kaplan-Meier(1) method) survival for all patients was 28.9 months after RFA treatment, and 44.6 months after the diagnosis of the colorectal liver metastases.

Jelle W. Kylstra, MD, Vice President and Medical Director of RITA Medical Systems, commented, "The Cleveland Clinic team is to be congratulated as its work builds a bridge between modern techniques for local control of metastatic colorectal liver cancer and recent advances in chemotherapy."

Dr. Kylstra continued, "The patients in this study, receiving both RFA to control disease in the liver and chemotherapy to contain systemic spread of their disease, lived on average 9 months to 16 months longer than patients in recently reported studies for colorectal cancer patients who received second-line chemotherapy or second-line chemo-biologic therapy alone. Clearly, patients fare best when offered the synergistic benefits of techniques such as RFA for optimal local control of tumor, combined with modern chemo-biological therapy for control of systemic disease."

The article authors noted that while surgical resection is still the gold standard for treatment, "only 10% to 20% of (colorectal liver metastases) patients are candidates for resection because of extensive disease or medical comorbidities." The authors also stated that, "of the more than 150,000 new cases of colorectal cancer reported in the United States each year, as many as 25% will have (colorectal) liver metastases at presentation and another 50% will develop liver (cancer) recurrence within the next five years."

The company noted that the results of the study may have the effect of expanding the population of patients with colorectal liver metastases considered candidates for the procedure because extra-hepatic disease was shown to not negatively impact survival. The cause of death, even among patients with extra-hepatic disease, was usually progression of disease in the liver.

The American Cancer Society estimates that 147,500 Americans were diagnosed with colorectal cancer in 2003, and further estimates that the disease claimed more than 57,000 lives in 2003.<sup>2</sup> The Company estimates that more than 70,000 colorectal cancer patients in the U.S. will develop colorectal metastatic liver cancer, and that more than 50,000 of these patients each year are candidates for RFA treatment. The Company estimates the total U.S. market opportunity for the treatment of colorectal liver metastases with RFA currently exceeds \$100 million annually.

An abstract of the article is available on the Journal of Clinical Oncology website, [www.jco.org](http://www.jco.org), by searching on the author's name, or article title. The full text article is also available to interested parties for a fee at the same internet address.

(a) For survival studies, the Kaplan-Meier estimate of survival is calculated by dividing time into intervals such that each interval ends at the time of an observation, whether censored (removed) or uncensored. The probability of survival is calculated at the end of each interval, with censored observations assumed to have occurred just after uncensored ones.

(b) American Cancer Society, "Cancer Facts and Figures 2003"

About RITA Medical Systems, Inc.

RITA Medical Systems develops, manufactures and markets innovative products for cancer patients including radiofrequency ablation (RFA) systems for treating cancerous tumors as well as percutaneous vascular and spinal access systems. The Company's oncology product lines include implantable ports, some of which feature its proprietary Vortex<sup>®</sup> technology; tunneled central venous catheters; safety infusion sets and peripherally inserted central catheters used primarily in cancer treatment protocols. The proprietary RITA system uses radiofrequency energy to heat tissue to a high enough temperature to ablate it or cause cell death. In March 2000, RITA became the first RFA Company to receive specific FDA clearance for unresectable liver lesions in addition to its previous general FDA clearance for the ablation of soft tissue. In October 2002, RITA again became the first company to receive specific FDA clearance, this time, for the palliation of pain associated with metastatic lesions involving bone. The RITA Medical Systems website is at [www.ritamedical.com](http://www.ritamedical.com).

The statements in this news release related to the size of the United States market for the treatment of colorectal liver metastases, efficacy of RFA treatment, survival rates resulting from the use of RFA or the RITA System, and benefits of RFA treatment for colorectal liver metastases are forward-looking statements involving risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. Information regarding these risks is included in the Company's filings with the Securities and Exchange Commission.

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