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RITA Medical Highlights Recent Clinical Publications Discussing Local Therapy Devices in the Treatment of Liver Tumors Associated With Colorectal Cancer

- Early Radiofrequency Ablation Treatment Demonstrates Encouraging Impact on Survival

- Chemoembolization Using Drug-Eluting Beads Shows Promise

- RITA RFA Devices Demonstrate Lower Local Tumor Recurrence Rate Versus Competitors

FREMONT, Calif., Oct. 3 /PRNewswire-FirstCall/ -- RITA Medical Systems, Inc. (Nasdaq: RITA), a publicly-traded medical device company focused solely on cancer therapies, today announced three recent publications discussing radiofrequency ablation (RFA) and embolization beads in the treatment of liver metastases associated with colorectal cancer (CRC).

In the first American study to report 5-year survival data for patients with unresectable CRC-related liver tumors treated with RFA, researchers demonstrated positive long-term benefits of this treatment. In a second study, conducted in Italy, encouraging preliminary reports were released for patients with extensive liver tumors associated with CRC and refractory after at least two prior chemotherapy regimens who had been treated with Biocompatibles International plc (LSE: BII) DC Bead™ embolization beads that had been "loaded" with the chemotherapy drug irinotecan and injected directly into tumor. The DC Bead is not cleared or approved in the U.S. for chemoelution. Finally, independent researchers in the Netherlands found favorable effectiveness (as measured by cancer recurrences at the site of radiofrequency ablation) of RITA electrode devices compared with those of two other manufacturers in the treatment of CRC metastases.

"Clinical studies continue to demonstrate the important role of RITA's medical device oncology products in the treatment of liver tumors related to colorectal cancers," said Joseph DeVivo, president and chief executive officer RITA Medical Systems. "These recent research publications are very encouraging in terms of assessing the long-term potential to safely and effectively improve the outcomes in patients with CRC liver metastases. We are also very excited about the early results of the Italian study using DC Bead to treat CRC liver metastases. Finally, we were very pleased with the independently funded and run study which found that RITA's expandable, deployable electrodes had a lower recurrence rate for colorectal metastases tumors compared with those of two of our competitors."

About Colorectal Cancer

Colorectal cancer is one of the most common malignancies in the U.S. and Europe with 500,000 new cases each year. In approximately 25% of patients, liver metastases are present at the time of diagnosis and eventually over 70% of patients will develop liver metastases. Only 20-30% of these patients are eligible for surgery and there remains a large group of patients for whom new treatments, such as local ablative techniques like RFA, are the only feasible alternatives.

Long-Term Outcome of RFA Treatment for Unresectable Liver Metastases from CRC (Machi J et el., The Cancer Journal 2006;12:318-326)

In a paper titled, "Long-Term Outcome of Radiofrequency Ablation for Unresectable Liver Metastases from Colorectal Cancer: Evaluation of Prognostic Factors and Effectiveness in First- and Second-Line Management", Junji Machi, MD, PhD, and colleagues from the Department of Surgery and Internal Medicine at the University of Hawaii and Kuakini Medical Center in Hawaii conducted a long-term follow-up of patients with liver tumors associated with CRC who received RFA treatment. The purpose was to evaluate the long-term outcome of RFA in conjunction with chemotherapy and to identify prognostic factors associated with survival.

RFA was performed for 100 patients in 146 procedures to ablate 507 colorectal metastatic tumors. All patients were followed up for at least 18 months up to 84 months or until death. The overall median survival was 28 months, and 1-, 3- and 5-year survival was 90.0%, 42.0% and 30.5%, respectively. This compares favorably with survival rates reported from other studies, in which patients who received chemotherapy treatment only, without concurrent use of local intervention. The authors concluded that RFA should be considered part of first-line management for unresectable CRC-related liver metastases.

Dr. Jelle W. Kylstra, Vice President and Medical Director at RITA, commented: "While numerous earlier studies had provided evidence of benefit of RFA in the treatment of unresectable liver metastases, no prior study had addressed the practical issue of timing of RFA in relationship to other treatments received by most patients, in particular chemotherapy. This study suggests that optimal cytoreduction upfront with methods such as RFA, followed by modern systemic chemotherapy, offers the best results. The results provide strong support for this concept of "multi-modality treatment" of metastatic colorectal cancer."

Use of Irinotecan-Eluting Beads in Treatment of Liver Metastases from CRC (Aliberti C et al., Anticancer Research 2006; 26:3779-82)

In a paper titled, "Trans-arterial Chemoembolization (TACE) of Liver Metastases from Colorectal Cancer Using Irinotecan-Eluting Beads: Preliminary Results," Camillo Aliberti, MD, Professor of Interventional Radiology at Delta Hospital in Ferrara, Italy, presented the preliminary results of a study to evaluate the feasibility of using irinotecan drug-eluting beads (DC beads, Biocompatibles UK Ltd.) administered intratumorally to patients with liver metastases from CRC. Irinotecan is a systemically active drug in the first- and second-line treatment of advanced CRC, and high-dose local treatment may be beneficial to patients refractory after systemic treatment. The objective of this study was to determine the safety, feasibility, tolerance and tumor response of TACE using irinotecan loaded DC beads for the treatment of unresectable liver metastasis in CRC patients.

Ten patients with liver metastases from CRC were treated with irinotecan- eluting beads at a dose of 100 mg every three weeks. Computed Tomography (CT) was performed 24 hours before and after TACE. The findings showed that TACE with irinotecan eluting beads was feasible and well tolerated. Right upper quadrant pain lasting four days was felt by all patients. After 30 days, a reduction of >50% of CEA levels (a marker used to diagnose or indicate recurrence of cancer) and of the lesional contrast enhancement was observed in all the patients.

Factors Influencing the Local Recurrence after RFA Treatment of CRC Liver Metastases. (van Duijnhoven et al., Annals of Surgical Oncology 2006;13:651- 658)

In a paper titled, "Factors Influencing the Local Failure Rate of Radiofrequency Ablation of Colorectal Liver Metastases", researchers at four academic and four large community based hospitals in the Netherlands presented results of a study designed to provide a prospective evaluation of the risk factors for local failure of RFA treatment of CRC liver metastases and to define exclusion criteria for RFA treatment of these metastases. Devices from three manufacturers were used in the study, including RITA Medical Systems, Radionics Cool-tip and Radiotherapeutics (now Boston Scientific).

A total of 199 lesions in 87 patients were ablated with 104 RFA treatments. These patients were not eligible for hepatic resections as a result of the tumors' locations, the number or size of the lesions or poor medical condition. Access was percutaneous in 31 treatments and by laparotomy in 73 treatments. RFA was combined with hepatic resection in 29 laparotomies.

Consistent with other studies, the research indicated that size and access route are significant factors in RFA failure rates. The study also suggests an influence of RFA electrode type on local recurrence. The local rate of recurrence at similar average original tumor sites for RITA devices was 26.8% as compared to 60.3% for the Radiotherapeutics (Boston Scientific) expandable electrode and 42.9% for the Radionics Cool-tip clustered triple electrode. Authors called the difference between the two types of expandable electrodes (RITA and Radiotherapeutics-BSC) remarkable, because >40 lesions of similar size were treated with each system. The study was independently conducted and not sponsored by RITA or any other RFA-systems manufacturer.

About RITA Medical Systems, Inc.

RITA Medical Systems develops, manufactures and markets innovative products for cancer patients including radiofrequency ablation (RFA) systems and embolization products 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® technology; tunneled central venous catheters; and safety infusion sets and peripherally inserted central catheters used primarily in cancer treatment protocols. The radiofrequency product line also includes the HABIB 4X resection device which coagulates a "surgical resection plane" and is designed to facilitate a fast dissection in order to minimize blood loss and blood transfusion during surgery. The proprietary RITA RFA 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 Company also distributes LC Bead embolic microspheres in the United States and Canada. The LC Bead microspheres are injected into selected vessels to block the blood flow feeding a tumor, causing it to shrink over time, and are often used in combination with radiofrequency ablation (RFA). The RITA Medical Systems website is at www.ritamedical.com.

The statements in this news release related to the number of patients in the United States and Europe with colorectal cancer who may be candidates for local ablative techniques, such as RFA; the safety and efficacy of RFA treatment; the safety of treatment with embolic beads; survival rates resulting from the use of RFA or the RITA System; the benefits of RFA treatment for colorectal liver cancer; and the benefits of embolic bead treatment for 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. Such risks and uncertainties include but are not limited to: the Company's ability to compete with companies offering alternative therapies for solid cancerous and benign tumors; the Company's lack of long-term data regarding the safety and efficacy of its RF and embolization products; delay of product introductions or modifications as a result of the FDA regulatory process; the Company's limited experience as a distributor of embolization beads; and the Company's success in its physician training efforts. Information regarding these risks and other risks and uncertainties is included in the Company's filings with the Securities and Exchange Commission.

SOURCE RITA Medical Systems, Inc.
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