

Rita Medical Systems Highlights Clinical Presentations at 2005 Radiology Society of North America 91st Scientific Assembly and Annual Meeting

Radiofrequency Ablation Treatment Shown to Improve Survival Rates and Patient Outcomes Across Multiple Organs

FREMONT, Calif., Dec. 1 /PRNewswire-FirstCall/ -- RITA Medical Systems, Inc. (Nasdaq: RITA), a publicly-traded medical device company focused solely on cancer therapies, today announced the presentation of several clinical studies featuring radiofrequency ablation (RFA) treatment of cancer at the Radiology Society of North America (RSNA) 91st Scientific Assembly and Annual Meeting in Chicago, Illinois. In addition to clinical information presented during plenary sessions at the annual meeting, approximately 200 physicians attended a symposium on interventional oncology presented by the RSNA and the Society of Interventional Radiology (SIR) Foundation.

Dr. Jelle Kylstra, Vice President and Medical Director of RITA Medical Systems commented, "Radiofrequency ablation was featured prominently at both the symposium and regular RSNA meeting this year, demonstrating in my view a determination among clinicians to expand the application of RFA in the treatment of cancer." Dr. Kylstra continued, "It is exciting to see 2-year, 3-year, and 5-year survival data being published with large patient series that I believe demonstrate comparable outcomes, and often with lower associated procedure morbidities than reported series of surgical candidates."

The Company believes that the RAPTURE lung cancer clinical trial data presented at RSNA is a starting point for comparative follow-on studies that may eventually lead to broader adoption of the procedure in the community based hospital setting. A description of the RAPTURE clinical trial data presented at the RSNA meeting is provided below.

Stuart Singer, MD, an interventional radiologist at Crouse Hospital in Syracuse, New York, said "I believe that the RAPTURE trial demonstrates that RFA for small primary and metastatic lung carcinoma is a viable treatment option for nonresectable patients with good intermediate survival results. I have had a comparable experience in my community hospital practice over the last 3 years in a similar cohort of patients."

RFA Treatment of Lung Cancer Clinical Data Presented

In a paper titled, "Radiofrequency Ablation of Pulmonary Tumors Response Evaluation (RAPTURE) Trial: 2-Year Survival Outcomes," author Riccardo Lencioni, MD, Professor of Radiology, University of Pisa, presented two-year survival outcomes from a lung RFA clinical study in which 186 lung tumors were treated in 106 patients. The study was a prospective, multicenter clinical trial. All 106 patients were non-surgical candidates with 33 presenting with primary non-small cell lung cancer (NSCLC), 53 presenting with colorectal cancer (CRC) metastases, and 20 presenting with metastases from other primary malignancies. Complete ablation of macroscopic tumor as evidenced at 3-month computed tomography (CT) was achieved in 173 of 186 tumors. No procedure-related deaths occurred. Overall survival was 69% at 1 year and 49% at 2 years in patients with NSCLC; and 86% at 1 year and 62% at 2 years in patients with CRC metastases. Cancer-specific survival was 91% at 1 year and 91% at 2 years in patients with NSCLC; and 88% at 1 year and 72% at 2 years in patients with CRC metastases.

In a paper titled, "Percutaneous Radiofrequency Ablation of Stage 1A Non-Small Cell Lung Cancer: A Prospective Multicenter Clinical Trial," author Prof. Lencioni, MD, focused on the biopsy-proven Stage 1 non-small cell lung cancer (NSCLC) patient data from the RAPTURE study reviewed above. 14 NSCLC patients were all considered unfit for surgery and radical radiotherapy. RFA was technically feasible in all 14 patients and a CT image obtained 1 month post-RFA showed a round, ground-glass density area encompassing the treated lesion in all cases. Complete ablation of the treated lesions was confirmed by the absence of tumor re-growth over a period of 1 year or more in 8 patients. Preliminary survival analysis by the Kaplan-Meier method showed 1 year and 2 year overall survival rates of 84% and 72%, respectively; and 1 year and 2 year cancer-specific survival rates of 92% and 92%, respectively.

The Company noted that in a series of 347 patients reported in the medical journal CHEST titled, "The Curative Treatment by Radiotherapy Alone of Stage 1 Non-Small Cell Carcinoma of the Lung" (S Gauden, J Ramsay, and L Tripcony Nov 1995; 108: 1278 - 1282), the largest such reported retrospective radiation therapy series in early lung cancer patients, patients with inoperable disease treated with definitive radiation therapy achieved an overall survival at 2 years of 54%. A copy of the abstract of the Gauden study may be found on the CHEST Journal website, <http://www.chestjournal.org>.

RFA Treatment of Liver Cancer Clinical Data Presented

In a paper titled, "Comparing the Outcomes of Surgical Resection and Radiofrequency Ablation in Cirrhotic Patients with a Single Small Hepatocellular Carcinoma and Well-Preserved Hepatic Function," author Prof. Riccardo Lencioni, MD, presented clinical data comparing surgical resection to percutaneous RF ablation in a matched case-control study. In the study 162 patients were matched and the rate of local tumor progression and the incidence of tumor recurrence were compared. Dr. Lencioni concluded that overall survival and rate of tumor recurrence was similar in the two groups. Although there was a higher rate of local tumor progression in the RF group in the study, RF ablation was "found to be as effective as surgical resection for the treatment of a single small hepatocellular carcinoma (HCC) in patients with well-preserved liver function."

In a paper titled, "Radiofrequency Ablation in Patients with Small (less than 4cm) Solitary Colorectal Liver Metastases," Allison Gillams, MD, Middlesex Hospital, London, UK, presented clinical data from a retrospective review of a sub-group of 35 patients from the institution's database of 221 patients with colorectal liver metastases treated with RFA. The 35 patients in the sub-group had a solitary liver metastasis, less than 4 cm in diameter. Survival data showed that median 3-year and 5-year survival from first ablation was 40 months, 65% and 43% respectively. The author concluded that "survival following RFA for small solitary colorectal liver metastases is extremely good."

The Company noted that in a series of 456 patients reported in the Journal of Clinical Oncology (Fong et al., JCO1997;15:938-946), 3-year and 5-year survival rates for patients with colorectal liver metastases treated with open liver resection were 59% and 38% respectively. The same study noted an overall complication rate of 24% following surgical resection, including a peri-operative mortality rate of 2.8%.

In a paper titled, "Complications after Percutaneous Radiofrequency Ablation (RFA) of Focal Hepatic Tumors," Ralf-Thorsten Hoffmann, MD, Professor of Radiology, University of Munich, Germany, reported study data assessing the number and degree of complications after RFA in patients suffering from liver tumors or metastases of the liver. Over a 5 year period 840 procedures were performed in 393 patients. 95 patients suffered from primary HCC, 126 had metastases of colorectal cancer, 124 of breast cancer, and 48 had metastases of other tumors. The size of tumors treated ranged from 5mm to 60mm (mean 27mm). Study data showed that the overall complication rate in the series was less than 5% with a major complication rate of about 1%. The author concluded that RFA is a "very safe therapeutical option for patients suffering from focal liver tumors."

RFA Treatment of Kidney Cancer Clinical Data Presented

In a paper titled, "Radiofrequency Ablation (RFA) of 25 Renal Masses in Patients with Solitary or Functionally Solitary Kidneys: Trends in Creatinine Levels with and without Obstructive Complications," Debra Gervais, MD, Director of Abdominal and Interventional Radiology at Mass General Hospital and an Assistant Professor of Radiology at Harvard Medical School, reported the results of a retrospective review of 141 tumors ablated in 125 patients. The study review revealed 25 tumors (median 3.1 cm) in 21 patients with solitary or functionally solitary kidneys. Complete ablation was achieved in 23 of 25 (92%) of tumors, with a mean follow up of 2.8 years during which no local recurrences were reported following complete necrosis of the tumor. The author concluded that "RF ablation of renal masses is a safe option for patients with solitary kidneys compared to surgical removal and in most cases preserves renal function sufficient to avoid dialysis."

RFA Treatment of Bone Tumors Clinical Data Presented

In a paper titled, "Radiofrequency Ablation: An Algorithm for the treatment of Spinal Mets and Myeloma," Gregory Gordon, MD, Department of Vascular and Interventional Radiology, Decatur Memorial Hospital, Decatur, Illinois, reported on the effectiveness RFA to reduce pain in 31 patients with 45 lesions. In the study 8 patients (25.8%) had a complete response (reduction in pain), 13 patients (42%) had a greater than 50% reduction in pain, and 7 patients (22.6%) had between 20% and 50% reduction in pain. The author concluded that "RFA is a promising new technique which helps in the treatment of pain from osteolytic metastases and myeloma," with an overall response rate in the series of greater than 90%.

In a paper titled, "Combination of Radiofrequency Ablation and Percutaneous Cementoplasty in Painful Bone Metastasis: Experience in 75 Cases," Afshin Gangi, MD, PhD, Professor of Radiology, University Hospital of Strasbourg, France, presented study results assessing the ability of the combination of RFA and cementoplasty to manage pain and consolidate load-bearing bone to prevent fractures. A total of 75 patients were treated for painful bone metastases by means of percutaneous RF ablation, with a mean tumor diameter of 4.5 cm. The author reported that "92% of the patients experienced a notable reduction in pain and an improvement in mobility within 24 to 72 hours."

RSNA and the SIR Foundation Present Week-Long Interventional Oncology Symposium Featuring Multiple Presentations on Radiofrequency Ablation

The use of RFA to treat several types of cancer was among procedures highlighted in a press release issued by the SIR

Foundation on Monday, November 28, 2005. Applications of RFA mentioned in the release included: RFA treatment of liver cancer; RFA treatment of bone tumors; RFA treatment of renal (kidney) tumors; and RFA treatment of lung cancer. The full text of the SIR Foundation press release may be found on the Society of Interventional Radiology website, <http://sirweb.org/news/news.shtml> .

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[®] technology; tunneled central venous catheters; and safety infusion sets and peripherally inserted central catheters used primarily in cancer treatment protocols. The 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 RITA Medical Systems website is at www.ritamedical.com.

The statements in this news release related to the efficacy, benefits and safety of RFA technology, including without limitation physician adoption of RFA treatment for lung, liver, kidney and bone cancer and other cancers, 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 with greater resources; the existence of alternative therapies that could prove to be superior to RFA; the lack of long-term data regarding the safety and efficacy of its RFA products; delay of product introductions or modifications as a result of the FDA regulatory process; 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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