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Breast Cancer Pilot Study Examines New Radiofrequency Ablation-Assisted Lumpectomy Breast Conservation Therapy

LITTLE ROCK, Ark. & MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)--Nov. 11, 2004--

Study to Determine Whether Procedure Can Reduce Re-Operative Rates

and Need for Additional Therapy Following Lumpectomy

The University of Arkansas for Medical Sciences (UAMS) and RITA Medical Systems, Inc. (Nasdaq:RITA) today announced that the first patient in a planned series of 30 received a radiofrequency ablation-assisted lumpectomy procedure.

The procedure is intended to give the patient a cancer-free area around the site where the tumor has been removed so that repeat lumpectomies are unnecessary. The procedure may also offer similar protection against recurrence provided by the use of partial or whole breast radiation, the current standard of care following lumpectomy.

The clinical study, "Pilot Study of Radiofrequency Ablation of Breast Cancer Lumpectomy Sites with Indocyanine Green Confirmation to Decrease Re-operation," is designed to determine the patient benefits of using radiofrequency ablation (RFA) to ablate, or sear, a one-centimeter margin or perimeter of soft tissue following standard lumpectomy removal of a breast tumor.

V. Suzanne Klimberg, M.D., Professor of Surgery and Pathology at the University of Arkansas for Medical Sciences (UAMS) and the Central Arkansas Veterans Healthcare Systems (CAVHS), Chief of the Division of Breast Surgical Oncology at UAMS, and Director of the Breast Cancer Program at UAMS' Arkansas Cancer Research Center (ACRC), will treat up to 30 patients in the Phase I clinical trial.

The treatments will be performed under the guidelines of the investigational review board (IRB)-approved pilot study with educational funding support provided in part by RITA Medical Systems of Mountain View, California. Additional support for the study will be provided by the Tenebaum Breast Cancer Research Program.

"Our goal is to change the way breast cancer is treated for the more than 100,000 women in the United States who undergo traditional lumpectomy for early stage breast cancer each year," Klimberg said. "Our initial research on donor mastectomy sections in the lab told us that RFA was effective in creating negative margins around small breast tumor. With the study we hope to prove that we can reduce the high re-operative rates associated with lumpectomy and offer added assurance that the cancer will not recur in these patients."

The researchers believe that giving patients a clear surgical margin at the time of the original lumpectomy will make unnecessary the estimated 40 percent of repeat lumpectomy procedures currently being done. The researchers also believe that the RFA-assisted lumpectomy procedure may offer similar protection against cancer recurring for some patients to the standard course of partial or whole-breast radiation therapy.

Joseph DeVivo, President and Chief Executive Officer of RITA Medical Systems, commented, "We are honored to partner with the University of Arkansas for Medical Sciences and its Arkansas Cancer Research Center and are pleased to support Dr. Klimberg's efforts. We believe the procedure holds great promise for breast cancer patients, and we are proud that RITA's current RFA offering is Dr. Klimberg's product of choice."

Under the IRB-approved prospective trial protocol patients will be treated with RFA at the time of initial lumpectomy. The success of the trial will be used to determine the feasibility of conducting a Phase II multicenter trial to evaluate the ability of RFA-assisted lumpectomy to decrease the rates of re-operation associated with standard lumpectomy. Qualified patients with operable breast cancer will be treated with a combination of two available and reliable treatments -- lumpectomy and RFA.

Before and after RFA is completed, fluorescence imaging will be used to ensure that no residual live cells remained in the ablation zone. Patients will be required to come in for follow-up visits at set intervals for a minimum of two years after the procedure. Long-term effects of the surgery and subjective cosmetic results will be recorded at each follow-up point. Initial

endpoints of the study will be the number of excisions avoided for focally positive margins and the accuracy of ablation of the area around the tumor bed.

An additional objective of the planned multicenter trial will be to show that the local recurrence rate will be reduced by using RFA-assisted lumpectomy. Because RFA will be administered in addition to procedures of demonstrated efficacy, it is expected the local recurrence rate will decrease. Although local recurrence rate is not the primary aim in this pilot study, patients still will be followed over time for local recurrence.

The large number of women treated for breast cancer each year supports the need for advances in treatment. Each year in the United States, an estimated 120,000 women receive standard breast conservation therapy, commonly referred to as lumpectomy. Of these patients approximately 40 percent require additional surgical treatment when pathology, typically reported two to five days following initial surgery, reveals the presence of cancer in the margins, the area surrounding the tumor. Also, only 10 percent to 40 percent of patients who are candidates for breast conservation therapy are receiving it, indicating the majority of women are undergoing some form of mastectomy (surgical removal of the whole breast), although several studies demonstrate equivalent outcomes for lumpectomy plus radiation therapy (RT) compared with mastectomy. Mastectomy also can result in significant psychological effects.

Whole-breast radiation therapy is currently recommended to most patients following lumpectomy to reduce the risk of recurrence at the surgical site. Radiation therapy is associated with substantial side effects during treatment, as well as late toxic effects and significantly decreases patient quality of life. The study will assist in the process of determining if RFA-assisted lumpectomy may be an option to reduce the risk of recurrence without the adverse physical and psychological effects of RT.

Another motivation to develop an alternative to RT is the number of patients who refuse to be treated with RT following lumpectomy. Estimates suggest that 30 percent to 40 percent of breast cancer patients choose not to receive RT due to fear about side effects and poor cosmetic results, and concerns about consequences of travel and impacts on their job or family. Radiation is typically given five days a week for five to seven weeks.

Jeanne Hite, 66, was diagnosed by breast biopsy in September 2003 with a small breast cancer tumor. She elected to receive RFA-assisted lumpectomy in March of 2004, prior to the start of the pilot study. Ms. Hite was reluctant to undergo the recommended six weeks of whole-breast radiation therapy, and at the suggestion of two consulting physicians contacted Dr. Klimberg to inquire about surgical options for her planned breast conservation procedure.

Ms. Hite commented, "I felt immediately comfortable with Dr. Klimberg's explanation of the procedure, and I am very pleased with the results. It was almost unbelievable how easy the treatment was: I went in early in the morning and by that afternoon I felt that I was cancer free. I was able to travel to California within two weeks of the procedure to help support my daughter while she was giving birth to her second child. I would have missed that experience completely had I needed to stay at home for the radiation treatments."

Ms. Hite continued, "I hoped that by adding radiofrequency ablation to my lumpectomy procedure I would be spared the possibility of having to undergo a second procedure and the need for radiation treatments. My follow up visits since March have shown no recurrence of the cancer and I am very thankful that I have not needed additional treatments."

"Jeanne's experience is exactly what we are hoping to repeat as well as capture and analyze in the controlled study," Klimberg said. "Many women are understandably anxious about possibly needing a second procedure to remove all of the cancer. We were able to confirm Jeanne's diagnosis and treat her on the same day."

Breast cancer remains the leading cancer diagnosis in women in the U.S. and will affect one in seven women in a woman's lifetime, with more than 215,000 new cases estimated to be diagnosed in 2004. About 59,000 more women will be diagnosed with a very early stage of the disease. Despite availability of breast-conserving surgery, only 10 percent to 40 percent of women in the United States who are candidates for this treatment receive it.

According to recent statistics, approximately 185,000 women diagnosed with early-stage breast cancer undergo one of the three most common surgical treatments: lumpectomy, lumpectomy with radiation or mastectomy. Each of these treatments is associated with a range of potentially negative physical and psychological effects, including cosmetic effects, toxicity and considerable risk of recurrence. RFA-assisted lumpectomy may allow improved cosmetic results with the best opportunity to ensure negative margins in patients with early-stage breast cancer.

Worldwide one in eight women will get breast cancer. Women with early-stage disease could potentially benefit from RFA-assisted lumpectomy. In 2002, more than 4.4 million women worldwide had some form of breast cancer with 1.2 million new

cases diagnosed. Breast cancer was the cause of death for more than 410,000 women worldwide in 2002.

UAMS and its Arkansas Cancer Research Center are recognized nationally and regionally for their commitment to advancing healthcare and cancer treatment for patients.

About University of Arkansas for Medical Sciences (UAMS)

UAMS is the state's only comprehensive academic health center, with five colleges, a graduate school, a medical center, five centers of excellence and a statewide network of regional centers. UAMS has about 2,170 students and 650 residents and is the state's largest public employer with almost 9,000 employees. UAMS and its affiliates have an economic impact in Arkansas of about $3.8 billion a year. UAMS centers of excellence are the Arkansas Cancer Research Center, Harvey and Bernice Jones Eye Institute, Donald W. Reynolds Center on Aging, Myeloma Institute for Research and Therapy and Jackson T. Stephens Spine and Neurosciences Institute.

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; 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 statements in this news release related to results of studies, the survival benefits of RFA-assisted lumpectomy and the Company's expectations regarding doctors' adoption of the technology for small breast tumors 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.

UAMS
http://www.uams.edu

ACRC
http://www.acrc.uams.edu/

RITA Medical Systems, Inc.
http://www.ritamedical.com

NOTE TO EDITORS: Please call to schedule in-person or telephone interview with Dr. Klimberg. BETA-SP video B-Roll of the actual surgery, surgeon and patient interviews is available upon request and by scheduled satellite feed. Contact Juliana Minsky, 805-962-3700.

This video news feed contains surgery, procedure animations & interviews with surgeon and patient

FEED DATE AND SATELLITE COORDINATES
Thursday, November 11, 2004 -- 2:00-2:15 PM ET
Tuesday, November 16, 2004 -- 10:00-10:15 AM ET

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