

Preliminary Results Demonstrate Feasibility of the Use of the RITA(R) System For Destroying Breast Tumors

MOUNTAIN VIEW, Calif., Nov. 28 /PRNewswire/ -- Preliminary results from a clinical feasibility study suggest that the RITA system can be used to safely ablate breast tumors. This feasibility study involved the ablation of small malignant breast tumors using radiofrequency energy delivered through the company's proprietary system. Bruno Fornage, M.D., who serves as the principal investigator for the clinical trial, presented the data Monday at the 86th Scientific Assembly and Annual Meeting of the Radiological Society of North America in Chicago, Illinois. Fornage is Professor of Radiology and Surgical Oncology at the MD Anderson Cancer Center.

The initial data was gathered on 10 patients diagnosed with malignant tumors who underwent ultrasound-guided radiofrequency ablation (RFA) with the RITA system immediately prior to their scheduled partial or total mastectomy. "Our goal was to demonstrate that this technique is applicable for the destruction of small breast cancers," said Dr. Fornage, "and this has been confirmed by our preliminary results which indicate 100% tumor death. At this time we are optimistic that this may some day become an alternative to surgery in selected cases."

A total of eleven malignant breast tumors ranging from 0.6 to 2 cm in size were ablated in 10 patients immediately before surgical resection using the RITA Model 500 Generator and Model 70 Device or the Model 1500 Generator and Starburst™ XL Device. Following partial or total mastectomy, each tumor was then thoroughly assessed for tumor cell death.

"We are very pleased to be working with one of the world's leading cancer institutes on this research," commented Barry Cheskin, President and CEO of RITA. "Although we recognize that additional clinical research will be required before we begin to promote our products for the ablation of breast tumors, we are very encouraged by the initial study results and consider this to be an important step in validating our platform technology in areas beyond the liver."

RITA Medical Systems develops, manufactures and markets innovative products for patients with solid cancerous or benign tumors. The proprietary RITA system uses radiofrequency energy to heat tissue to a high enough temperature to ablate it or cause cell death. The company has sold over 15,000 of its disposable devices throughout the world. While the company's current focus is on liver cancer, the company believes that its minimally invasive technology may in the future be applied to other types of tumors, including tumors of the lung, bone, breast, prostate and kidney. The company has received regulatory clearance in major markets worldwide, including the United States. In March 2000, RITA became the first radiofrequency ablation company to receive specific FDA clearance for unresectable liver lesions in addition to its previous general FDA clearance for the ablation of soft tissue. The RITA system does not have a specific FDA clearance for the ablation of breast tumors.

The statements in this news release related to the company's plans to extend its technology to applications beyond the liver are forward-looking statements involving risks and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties could include, but are not limited to, the company's need to achieve market acceptance of the RITA system, the company's current lack of long-term clinical data regarding the safety and efficacy of its products, significant competition in the company's industry, alternative therapies which could prove to be superior to the RITA system, the need to establish reimbursement from payors, potentially costly and time-consuming product liability actions, the company's need to train physicians and the requirement that the company comply with applicable FDA and other regulations. Further information regarding these and other risks is included in the company's S-1 registration statement and other recent filings with the Securities and Exchange Commission, including the company's Report on Form 10-Q for the quarter ended September 30, 2000.

NOTE: RITA and StarBurst are trademarks of RITA Medical Systems, Inc.

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