

RITA Medical Initiates Feasibility Study of Device for RFA-Assisted Breast Lumpectomy

First Three Clinical Cases Using the Investigational Starburst Assure(TM) RF Electrode Performed

FREMONT, Calif., Oct. 26 /PRNewswire-FirstCall/ -- RITA Medical Systems, Inc. (Nasdaq: RITA), a publicly-traded medical device company focused solely on cancer therapies, today announced that the initial three clinical cases in the RFA-assisted Lumpectomy feasibility study were performed. The procedures used the Company's investigational Starburst Assure™ RFA electrode to ablate the wall of the lumpectomy cavity of patients undergoing breast conserving surgery, immediately following excision of the primary tumor. The feasibility study is designed to study the potential of RFA-assisted lumpectomy in sparing women the necessity and trauma associated with additional surgery when close or inadequate margins are identified through pathology examination following lumpectomy procedures.

The procedures were performed by Dr. Antonio Piga and Dr. Carlo Cabula at the Ospedale Oncologico in Cagliari, Sardinia, Italy.

Joseph DeVivo, President and CEO of RITA commented, "The Assure device is a novel RFA electrode designed specifically for the breast by our research and development team and this feasibility trial is the first step in our efforts to commercialize this new device. The start of the trial is a very important milestone for RITA and we are very grateful to Drs. Piga and Cabula and the entire team who performed these first-ever clinical cases. Our next milestone is to complete enrollment in this study which we believe we can do on schedule."

The RFA-assisted Lumpectomy feasibility study is intended as a multi-center study that will include patients from four centers in Italy. Following surgery, comprehensive pathological testing is conducted to characterize multiple aspects of device performance, such as to ensure conclusively the presence of a tumor-free margin in the lumpectomy cavity.

Dr. Jelle W. Kylstra, Vice President and Medical Director at RITA, commented: "We are very pleased that three initial procedures with the Assure device have been performed. We believe that the Assure device functioned as anticipated during the procedures and we look forward to completing enrollment and ultimately to evaluating the final pathology data relating to these and future procedures. With the start of this trial, we take the development program for RFA-assisted lumpectomy to an international level."

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. 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 RFA. The RITA Medical Systems website is at www.ritamedical.com.

The statements in this news release related to the potential outcomes for breast cancer patients treated with RFA-assisted lumpectomies and the continuation of the RFA assisted lumpectomy feasibility study 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 data regarding the safety and efficacy of the investigational Starburst Assure radiofrequency electrode; and delay of product introductions or modifications as a result of the FDA regulatory process. 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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