

## FDA Clears RITA Medical Systems Radiofrequency Ablation Technology

## For Relief of Pain From Bone Tumors

## Study Led by Mayo Clinic Showed Patients Experienced Significant and Lasting

## **Reductions in Debilitating Pain**

MOUNTAIN VIEW, Calif., Oct. 21 /PRNewswire-FirstCall/ --

RITA Medical Systems, Inc. (Nasdaq: RITA) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its proprietary radiofrequency (RF) ablation technology to provide cancer patients with relief from the pain that often occurs when cancer spreads, or metastasizes, to the bone. The FDA clearance follows a clinical study of the effectiveness of RITA's RF system for the relief of pain from bone tumors conducted at nine medical centers in the United States and Europe and presented recently at the Annual Meeting of the American Society of Clinical Oncology (ASCO). The study, led by a team of physicians at Mayo Clinic, showed that 95 percent of the patients treated with the RITA RF procedure experienced a clinically significant reduction in pain from bone tumors.

The most common site of the spread of cancer is the bone, and as many as 50 percent of patients with this condition suffer debilitating pain that is not adequately relieved by any conventional means. The new clearance enables the company to specifically market the technology as a means of relieving pain caused by metastatic bone tumors in these patients and opens a new market for RITA's RF system that is estimated by the company at \$600 million annually worldwide.

William Charboneau, M.D., a radiologist at Mayo Clinic in Rochester, MN and the senior investigator of the recent study on which the FDA clearance was based, said the study shows that the RITA RF system provides physicians a new alternative for pain reduction, or palliation. According to Dr. Charboneau, Our study provides evidence that even the most challenging cancer pain involving bones can be effectively and safely controlled when the cancer is limited to one or two sites in the bone. Most importantly, these patients will likely have a markedly improved quality of life after the RF ablation treatment.

The 43-patient study demonstrated that the RF system offered rapid and durable pain relief. Patients were asked to report their pain on a standard 10-point pain rating scale before and after the procedure with 10 being pain 'as bad as you can imagine.' Of the 43 cancer patients enrolled in the study, 41 experienced a clinically significant reduction in the severity of their pain after a single treatment. The majority of the 41 patients reported significant pain relief within the first week after their treatment and said the relief increased in subsequent weeks. More than 75 percent of patients experienced 90 percent or more pain relief at some point during the study. Follow-up on these patients indicates they continue to enjoy significant pain relief up to six months after their RF treatment.

Barry Cheskin, RITA's President and Chief Executive Officer, said the clearance by the FDA is important news for his company and for cancer patients around the world. It is especially satisfying to see the dramatic impact this procedure has on the lives of the patients involved in the clinical studies, Cheskin said. For these people, and hundreds of thousands of cancer patients worldwide, there is a new option and new hope for enhancing their quality of life.

Cheskin added that the FDA clearance also opens a brand new and significant market for RITA which is as large or larger than our existing market for liver cancer. The company expects a limited commercial introduction of the product for relieving pain from bone tumors by the end of 2002 followed by a more comprehensive launch in the first quarter of next year.

RITA's RF system enables physicians to deliver RF energy into the tumor tissue through an array of thin electrodes that heat and effectively destroy, or ablate, the targeted tissue. In many cases, this minimally invasive procedure can be performed in an outpatient setting or with just an overnight stay.

About RITA Medical Systems, Inc.

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. While the Company's current focus is on liver cancer and metastatic bone 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, breast, uterus, 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. 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 has sold approximately 40,000 of its disposable devices throughout the world.

The statements in this news release related to the company's plans to extend its technology to applications beyond the liver and the company's projections of the market potential related to liver and non-liver applications 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 and other risks is included in the Company's filings with the Securities and Exchange Commission.

RITA is a trademark of RITA Medical Systems, Inc.

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(RITA)

CO: RITA Medical Systems, Inc.; U.S. Food and Drug Administration; FDA;

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