

## **Dune Medical Completes Enrollment in MarginProbe™ Pivotal Trial for Real-Time Detection of Cancer During Breast Conservation Surgery**

**New York, January 12, 2010** -- Dune Medical Devices today announced the completion of patient enrollment in the MarginProbe™ pivotal clinical trial. The MarginProbe procedure provides surgeons with real-time detection of cancer at the edges of the tissue removed during breast conservation surgery (BCS), which is the only way to ensure the complete removal of the tumor from the breast. The randomized, controlled trial includes 664 women who underwent BCS at one of 21 leading medical facilities, with 18 in the US and three in Israel.

“This trial is one of the largest randomized, controlled trials for intraoperative margin assessment ever undertaken. Completing enrollment in only 15 months is a significant accomplishment,” said lead investigator Lorraine Tafra, MD, FACS, Medical Director of Anne Arundel Breast Center, Annapolis, MD. “Because of the importance of achieving clear margins in BCS and the potential of MarginProbe to improve upon existing standards, we eagerly anticipate the trial results. Such a rigorous trial has the potential to help us in the development of better breast surgery techniques.”

The main surgical objective of BCS is the removal of the primary tumor with a rim of healthy tissue, known as the margin, preferably in one surgical session. According to the medical literature, between 20 percent and 40 percent of BCS patients require a second surgery because clear margins were not achieved during the initial procedure. Dune's real-time, cancer detection procedure is designed to give surgeons a simple, instant indication of the presence of cancer at the margins, allowing for its immediate removal.

“This is a significant milestone in our mission to reduce the need for multiple surgeries to treat breast cancer,” said Dr. Dan Hashimshony, founder and CEO of Dune Medical Devices. “The intent of this trial was to obtain a rigorous and ample body of data that demonstrates the capacity of our technology to improve surgical oncology practice and outcomes. We are grateful to everybody involved in this significant clinical trial, including physicians, nurses, staff, and especially the patients.”

### **About MarginProbe**

The MarginProbe system comprises a single-use probe and a portable console. During breast cancer surgery, the surgeon utilizes the probe to apply radio frequency signals to excised tissue specimens. The reflections of these signals are captured by the probe, compared to a pre-defined criteria, and characterized as positive or negative for cancer at the tissue margins. With simple operation and instantaneous results, the procedure easily integrates into existing surgical workflow.

In October 2008, *American Journal of Surgery* published results of a 300-patient, randomized, controlled clinical trial designed to study the benefit of MarginProbe in intraoperative margin assessment for BCS and the associated reduction in second surgeries. In the treatment group, surgeons applied the MarginProbe to excised tissue

specimens and re-excised additional tissue according to the device's readings. The second surgery rate was significantly reduced by 56 percent with use of MarginProbe.

### **About Dune Medical Devices**

Founded in 2002, Dune Medical Devices envisions improving the performance and outcomes of a broad range of diagnostic and therapeutic procedures through the application of its tissue characterization technology, which provides a real-time indication of a tissue's status.

Dune's initial focus has been surgical oncology, where it is engaged in the development and commercialization of intraoperative systems intended to identify cancerous tissues, thereby enabling immediate removal and cancer-free surgical results. The MarginProbe system is CE marked for use in breast cancer surgery.

Dune Medical Devices is a privately-held company, financed by Apax Partners. It has offices in New York, Israel, and Switzerland.

For more information, please visit [www.dunemedical.com](http://www.dunemedical.com).

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