FDA Advisory Panel Votes in Favor of Dune Medical Devices MarginProbe@ System

The Associated Press

Dune Medical Devices announced today that a U.S. Food and Drug Administration (FDA) Advisory Panel voted (10 to 1) in favor of Dune's MarginProbe System for use in breast cancer surgery, as an adjunct to current standard methods of intraoperative surgical margin assessment.

Dune submitted a Premarket Application (PMA) in April 2011 based on data from a 600 patient pivotal study conducted primarily in the U.S.

"We are very pleased with the panel's positive decision on the MarginProbe System for use in the U.S.," says Dune's Chief Executive Officer Dan Levangie. "We believe that the MarginProbe System will give surgeons a powerful tool in their fight against breast cancer and provide women a substantially better chance of avoiding additional surgeries. We will work closely with the FDA to complete the approval process and intend to launch the MarginProbe System in the U.S.

immediately thereafter." Historically, between 30%-60% of women who undergo breast conservation surgery have to undergo additional surgeries because doctors fail to achieve negative margins during the first surgery. The pivotal trial data shows that by using The MarginProbe System during the first operation, in conjunction with standard methods, surgeons will have the ability to significantly reduce the rate of positive margins following the initial surgery.

About the MarginProbe System The MarginProbe System enables real time detection of cancer at or near the surface of excised tissue specimens during surgery for breast cancer. The simple and immediate assessment of the surgical margins allows surgeons to immediately excise additional tissue, significantly reducing the potential for positive margins remaining after the initial lumpectomy.

About Dune Medical Devices Dune Medical Devices was founded in 2002 by Dr. Dan Hashimshony to realize the extraordinary medical potential of its proprietary tissue characterization technology. Offering surgeons and radiologists the real time ability to identify cancerous tissues and react immediately, this technology holds the promise for a broad range of surgical and diagnostic applications. The MarginProbe System is Dune's first commercial product and is commercially available in Europe. The MarginProbe device is an investigational device that is not yet available for sale in the U.S.

Dune Medical Devices is a privately held company financed by Apax Partners since 2004. It has offices in the U.S., Israel, and Switzerland. For more information, please visit www.dunemedical.com Contact: Michael Graffeo, Director of Marketing, Dune Medical Devices 508-620-2782 / michael.graffeo@dunemedical.com Dave

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