Dune Medical Devices Receives Approvable Letter from FDA for the MarginProbe@ System

The Associated Press

Dune Medical Devices, Inc., announced today that it has received an Approvable Letter for its Premarket Approval Application (PMA) from the Food and Drug Administration. The Approvable Letter states that the MarginProbe System PMA is approvable subject to final agreement with FDA on the design of the required Post Approval Study.

"We are delighted to have come to this point in the approval process with FDA and will work diligently over the coming weeks to develop the final design of the Post Approval Study. Having completed our discussions with FDA related to product labeling, the Post Approval Study is the only remaining issue to be resolved prior to final approval," said Daniel Levangie, Chief Executive Officer of Dune Medical Devices.

About Early-Stage Breast Cancer Treatment Breast cancer is the most common type of cancer affecting women in the U.S., with over 285,000 women diagnosed each year.[i] Increased breast screening awareness and advancements in imaging technology such as mammograms now catch more breast cancer cases in earlier stages, when they are most treatable.

In fact, over half of all breast cancer diagnoses are for early-stage cancers. Many of these cases are non-palpable, meaning a tumor cannot be felt during a breast exam.

It is estimated that 60 to 75 percent of breast cancer cases will undergo a lumpectomy procedure as their initial treatment versus mastectomy, which involves the removal of the whole breast. Lumpectomy in combination with radiation therapy is as effective in combating breast cancer as mastectomy, as long as no cancer cells are present on the rim or edge of the removed tissue, also known as "clean margins." Research shows there is no significant difference in overall survival between the two procedures;[ii],[iii] however, if there is cancer at the edge, or a "positive margin," the risk of recurrence increases significantly.

Following a lumpectomy, surgeons will send the removed tissue to the pathology lab where it is analyzed for cancer on the margin. This is critical information because if there is cancer present on the edges of the removed tissue, there is a possibility that cancer still remains in the breast. Once a tissue sample is sent to pathology for analysis, it can take approximately one week or more to receive the lab results that determine if the patient must undergo a repeat surgery.

Inability to know if all cancerous cells have been removed from the breast during the initial lumpectomy procedure results in repeat surgery rates ranging from 30 to

60%.[iv] 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.

Dune Medical Devices is a privately held company financed by Apax Partners since 2004. It has offices in the U.S., Israel, Germany and Switzerland.

Contact: Michael Graffeo Dune Medical Devices Michael.graffeo@dunemedical.com (508) 620-2782 Kimberly Muscara The Ruth Group kmuscara@theruthgroup.com (646) 536-7011 [i] American Cancer Society: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-030975.pdf [ii] Fisher B, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. N Engl J Med.

2002;347(16):1233-1241.

[iii] Fisher B, et al. Twenty-year follow-up of a randomized trial comparing total mastectomy, lumpectomy, and lumpectomy plus irradiation for the treatment of invasive breast cancer. N Engl J Med.

2002;347(16):1233-1241.

[iv] Journal of the American Medical Association: http://jama.jamanetwork.com/article.aspx?articleid=1104931#Abstract SOURCE Dune Medical Devices -0- 11/19/2012 /Web Site: http://www.dunemedical.com CO: Dune Medical Devices; Food and Drug Administration (FDA) ST: Massachusetts IN: HEA MEQ SU: FDA PRN -- NE15664 -- 0000 11/19/2012 13:00:00 EDT http://www.prnewswire.c

Source URL (retrieved on *01/26/2015 - 6:07pm*):
http://www.mdtmag.com/news/2012/11/dune-medical-devices-receives-approvable-letter-fda-marginprobe-system