Dune Medical Devices Receives FDA Approval for Breakthrough Advancement in Breast Cancer Surgery

The Associated Press

Dune Medical Devices, Inc., announced today that its breakthrough intra-operative tissue assessment tool for early-stage breast cancer surgery, the MarginProbe System, has received Premarket Approval (PMA) by the United States Food and Drug Administration. The technology significantly improves surgeons' ability to intra-operatively identify "cancer on the margin" and significantly reduce pathologically positive margins following a patient's initial lumpectomy surgery.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/58891-dune-medical-devices-fda-approval-margi... [1] FDA approval of the MarginProbe System was based on a 664 patient prospective, multi-center, randomized, double arm study to evaluate the effectiveness of MarginProbe in identifying cancerous tissue along the margins of removed breast tissue during initial lumpectomy procedures. MarginProbe, which uses electromagnetic "signatures" to identify healthy and cancerous tissue, was found to be over three times more effective in finding cancer on the margin during lumpectomy, compared to traditional intra-operative imaging and palpation assessment. This enabled surgeons to significantly reduce the number of patients with positive margins following initial surgery.

"Up to this point our ability to assess the microscopic margin status in the operating room has been limited. Frequently, early-stage breast cancers are detected by mammography. This can make the process of achieving negative margins more challenging," said Dr. Susan K.

Boolbol, an investigator for the pivotal clinical trial and Chief of Breast Surgery at Beth Israel Medical Center. "Following their breast cancer surgery, telling a patient that they need more surgery can be an emotional issue for doctors and patients. This may result in tremendous anxiety and frustration. I believe that the MarginProbe System can help advance the field of breast surgery." It is estimated that 30 to 60 percent of early-stage breast cancer patients who have an initial lumpectomy procedure will undergo a repeat surgery.[i] This is because cancerous cells are found to be present on the rim or edge of the removed tissue, increasing the possibility that cancer still remains in the breast.

Susan Scanlan, breast cancer survivor and Chair of the National Council of Women's Organizations, said, "When I was first diagnosed with breast cancer I decided to undergo a lumpectomy, but like many others, I was told I had cancer on the margin following the procedure.

The mental distress of having to go back for a repeat surgery undermined my

confidence. I believe MarginProbe offers women the additional peace of mind that they can move on to the next step in fighting the disease and put breast cancer in their rearview mirror." "The MarginProbe System was developed to address one of the longest standing unmet medical needs in the breast cancer surgical community," said Daniel Levangie, Chief Executive Officer of Dune Medical Devices.

"We have received resounding support from clinicians, advocacy organizations and patients alike, who have recognized the value of MarginProbe and intra-operative, real-time detection of cancer on the margin to potentially improve patient outcomes." MarginProbe has been available in Europe since 2008 and is now available in select locations throughout the U.S., with national availability expected in early 2013. For more information, please visit www.dunemedical.com [2].

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.[ii] 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 in 60 to 75 percent of breast cancer cases, patients will undergo a lumpectomy procedure as their initial treatment versus mastectomy, which involves the removal of the whole breast[iii]. 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;[iv] 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%.

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 [3] (508) 620-2782 Kimberly Muscara The Ruth Group kmuscara@theruthgroup.com [4] (646) 536-7011 [i] Journal of the American Medical Association: http://jama.jamanetwork.com/article.aspx?articleid=1104931#Abstract [5] [ii] American Cancer Society: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/docume... [6] [iii]Journal of the American Medical Association: http://jama.jamanetwork.com/article.aspx?articleid=1104931#Abstract [5] [iv] 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.

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