

EDAP Receives U.S. FDA Filing Acceptance of Pre-Market Approval Application

GlobeNewswire

LYON, France, March 28, 2013 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:[EDAP](#) [1]), the global leader in therapeutic ultrasound, announced today that the U.S. Food and Drug Administration has provided a positive Filing Review Notification on the Company's Pre-Market Approval (PMA) application for its Ablatherm Integrated Imaging HIFU (High Intensity Focused Ultrasound) device for the treatment of low-risk, localized prostate cancer. The FDA conducted a filing review of EDAP's PMA, and found it to contain all of the information needed to proceed with the substantive review, in which the FDA will evaluate the safety and effectiveness of Ablatherm Integrated Imaging HIFU device, as well as EDAP's engineering, manufacturing and quality systems.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented, "Receiving FDA filing acceptance for our PMA in less than two months is both very timely and a major milestone. We are moving forward in the PMA Review Process as the agency commences its substantive review. We will continue to work closely with the FDA review team."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer, and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial conducted under an Investigational Device Exemption (IDE) granted by the FDA. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith® range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <http://www.edap-tms.com> [2], and <http://www.hifu-planet.com> [3].

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