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EDAP Outlines Key Events Scheduled in the Ablatherm-HIFU PMA Process

LYON, France, May 27, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today provided additional details on key events scheduled as part of the U.S. Food and Drug Administration (FDA) Pre-Market Approval ("PMA") process for its Ablatherm-HIFU device for the treatment of localized prostate cancer.

In addition to the previously announced panel of experts that is scheduled to review the Ablatherm-HIFU device and provide a recommendation based on the clinical data submitted to the FDA, the Company has additional milestones to achieve as part of the PMA application process. The first relates to an engineering, manufacturing and quality assessment of EDAP's factory, which consists of a routine inspection by the FDA. This has now been confirmed and scheduled to take place June 23 to June 26, 2014. In parallel there is a clinical data validation process, which includes an FDA audit of the investigation sites. The Company has received confirmation and scheduling of the "foreign" site's audit which will be conducted in the course of July 2014.

Marc Oczachowski, EDAP's Chief Executive Officer, said, "Having dates confirmed for these additional milestones is further great news for EDAP, as it demonstrates how quickly the FDA process is moving for our Ablatherm-HIFU PMA application. We are very enthusiastic to see the progression of events since our last complete submission in March of this year and consider this to be a very exciting time in the Company's history. Our experienced team is fully committed to preparing for these upcoming events so that we can execute these optimally. EDAP has successfully met the requirements of all of our previous FDA inspections and audits and is professionally organized in compliance with major quality assurance systems."

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 under an Investigational Device Exemption (IDE) granted by the FDA. In February 2013, the Company introduced a new innovative HIFU device, the Focal One® dedicated to focal therapy of prostate cancer. Focal One® is CE marked but is not FDA approved. 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, and http://www.hifu-planet.com.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements.. Such statements00 are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others the uncertainties of the U.S. FDA approval process, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device.,. Factors that may cause such a difference also may include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

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