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EDAP Receives Feedback From FDA on Direct De Novo 510(k) Petition for Ablatherm HIFU

LYON, France, July 21, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that it has received a letter from the U.S. Food and Drug Administration ("FDA") related to its Direct De Novo 510(k) petition for Ablatherm HIFU in the United States. The "Deficiency List" (as such communications about a regulatory filing are officially termed), identifies items and topics for which the FDA has requested additional information or further clarification to continue its ongoing review. Only four (4) points were raised in the deficiency list, and the FDA requested (1) the results of EDAP's reprocessing validation tests (which are ongoing and expected to be completed in the near future), (2) additional information regarding the Company's physician training program, (3) additions and modifications to the draft labeling materials, and (4) additions and modifications to the draft user manual.

In accordance with the De Novo process, the FDA's review of the Ablatherm HIFU submission is on hold until EDAP provides information to address these requests. The company is working to provide the necessary information and clarifications as expeditiously as possible.

Marc Oczachowski, Chief Executive Officer of EDAP TMS SA, commented: "We are very pleased with the FDA feedback to our De Novo 510k submission. We believe we can address each of the issues raised and we look forward to continuing to work closely with FDA to move the process forward."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer outside the U.S. 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 for commercial distribution in Europe and some other countries including Mexico and Canada. EDAP TMS is currently pursuing a Direct De Novo 510(k) petition in lieu of a PMA for Ablatherm clearance by the U.S. FDA. The Company also markets an innovative robot-assisted 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 distributes medical equipment (the Sonolith® lithotripters' range) for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL) in most countries including Canada and the U.S. 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 statements 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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