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EDAP Announces CMS Approval of New Reimbursement Code for HIFU Ablation of the Prostate

- Billing code will take effect July 1st, 2017

LYON, France, May 22, 2017 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the Centers for Medicare and Medicaid Services (CMS) have established a new billing code for HIFU ablation of prostate tissue.

A photo accompanying this announcement is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/a94c40ad-b3a4-4d46-a5e7-a73a4873fcf9

EDAP Ablatherm HIFU Device

HIFU for prostate tissue ablation

"We are elated by CMS's decision," said Marc Oczachowski, EDAP's Chief Executive Officer. "This is another key milestone in the acceptance and recognition of HIFU technology in the U.S. as reflected by CMS's celerity in addressing the dossier, establishing a c-code and assigning a competitive coverage level. It will provide a choice between recognized therapies based solely on clinical need and evidence. The C-code is a significant achievement and opens the door to broader coverage from different payers, including private and commercial payers. We will now transition our efforts toward expanding coverage and physician education to make our innovative technology available to all patients in the U.S."

HIFU ablation of prostate tissue procedures have been assigned C-code 9747 - ambulatory payment classification (APC) 5376; the code will take effect July 1st, 2017. C-codes are unique, temporary pricing codes initially established for the Hospital Outpatient Prospective Payment System (OPPS). The C-codes are used on Medicare OPPS claims, and may also be recognized on claims from other providers or by other payment systems. The code is applicable to all procedures performed by the Company's HIFU devices, including whole primary whole gland prostate ablation, partial prostate ablation or whole and partial salvage ablation.

Mr. Ozachowski added, "I would like to thank Jerry Stringham, president of the reimbursement strategy consulting firm Medical Technology Partners for all of his hard work. Jerry has been instrumental in directing our efforts towards reimbursement. We look forward to continuing to work with his experienced team while we pursue additional reimbursement for HIFU procedures."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm® for high-intensity focused ultrasound (HIFU) for prostate tissue ablation in the U.S. and for treatment of localized prostate cancer in the rest of the world. HIFU treatment is shown to be a minimally invasive and effective option for prostatic tissue ablation 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, and has received 510(k) clearance by the U.S. FDA. Ablatherm Fusion is not FDA cleared yet. 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 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.

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