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EDAP Receives Russian Regulatory Approval for Focal One(R) HIFU Device

LYON, France, Dec. 11, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that Russia's Federal Service for Surveillance in Healthcare (Roszdravnadzor) has approved Focal One for sale in Russia. Russia is currently the largest market for EDAP's Ablatherm® robotic HIFU technology.

Marc Oczachowski, EDAP TMS Chief Executive Officer, commented: "This is another important milestone for EDAP and its Focal One technology, and a significant advancement for Russian patients who will now have access to our next-generation focal HIFU treatment for prostate cancer. Focal One will well complement EDAP Robotic HIFU offering in Russia, where we already gather our largest installed base of Ablatherm devices."

Focal One combines the latest imaging modalities with EDAP's proprietary, cutting-edge HIFU technology into one unique device. Focal One combines the latest improvements of MRI in the diagnosis of prostate cancer with precision HIFU and a high performance ultrasound tool to validate treatment efficiency. These characteristics make Focal One the first device to address the need for an optimal focal therapy for prostate cancer while preserving patient quality of life.

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. 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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