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EDAP Announces Focal One(R) HIFU Sale to Clinica Santa Maria de Santiago de Chile

First Focal One(R) Device Sold in Latin America

LYON, France, Nov. 10, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced the acquisition of a Focal One system by Clinica Santa Maria, Santiago de Chile, one of the country's largest groups of private urology clinics.

Dr. Alfredo Velasco P., Head of the Urology Department and robotic surgeon at Clinica Santa Maria, commented: "Addressing prostate cancer is a major challenge for Urologists today. We clearly see positive advances in technologies such as Focal One that allow for less invasive treatments with minimal side effects for patients. Innovations in imaging technologies have led to the emergence of the focal approach in the treatment of localized prostate cancer. With the early detection of prostate cancers and ability to identify smaller cancerous areas, traditional robotic surgery, radiotherapy and brachytherapy are no longer suitable to address these little, early-stage, tumor cells. This is why, to remain at the forefront in the treatment of prostate cancer, Clinica Santa Maria decided to add Focal One HIFU to its existing state-of-the-art therapeutic arsenal in urology."

Marc Oczachowski, EDAP's Chief Executive Officer, added: "We are very pleased with the sale of our first Focal One HIFU device in Latin America. EDAP is well established in this region of the world via a large installed base of Lithotripters and Ablatherm Robotic HIFU systems. A great number of Latin American patients have already benefited from Ablatherm HIFU, and the introduction of Focal One at one of the region's largest urology groups will increase the range of therapeutic options and allow patients access to the cutting edge focal approach to prostate cancer management."

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 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. EDAP TMS has submitted a 510(K) notice 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 clearance 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 is not FDA-cleared or marketed in the United States.

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