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EDAP Receives Japanese Approval for Quanta Litho Laser; Secures Exclusive Distribution Rights in Japan

LYON, France, Jan. 06, 2016 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that its Japanese subsidiary, Edap Technomed Japan, has secured Japanese PMDA approval for the Quanta Litho Laser. By gaining this approval, Edap Technomed Japan has been granted exclusive marketing and distribution rights in Japan by Quanta System SpA.

Jean-François Bachelard, General Manager of EDAP Technomed Japan, commented: "We are very pleased with the grant of this approval by the Japanese PMDA as it allows EDAP to immediately and exclusively distribute the Litho Laser in the Japanese Territory. This laser is a clear complement to our existing range of urology products and technologies, further expands our comprehensive therapeutic offering in the management of stone diseases."

Paolo Salvadeo, Chief Executive Officer of Quanta System SpA, added: "This regulatory approval is a milestone achievement for both EDAP and Quanta, which we believe will further strengthen the global cooperation between our companies.Â The economy of Japan is the third largest in the world by nominal GNP, the fourth largest by purchasing power parity and is the second largest developed economy. Based on this large market opportunity, we are pleased to have EDAP play an even more significant role in the continued development of our urology business by marketing our gold standard Litho Laser in Japan."

Marc Oczachowski, EDAP TMS Chief Executive Officer, concluded: "This is an important step forward in our productive, worldwide collaboration with Quanta System. Moreover, this clearance further validates EDAP's ability to work through international regulatory processes and guidance to successfully achieve marketing approvals for innovative technologies and devices. We look forward to bringing the Litho Laser technology to the Japanese market."Â

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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