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EDAP Retains Greenleaf Health as Strategic Advisor on U.S. FDA Submission

Strengthens Team for Final Stages of Ablatherm-HIFU Phase II/III Clinical Trial for Prostate Cancer

LYON, France, Aug. 29, 2012 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced the retention of Greenleaf Health LLC, a full service regulatory consulting firm. Greenleaf Health will provide the Company with high-level strategic guidance regarding the final stages of its Ablatherm-HIFU (High Intensity Focused Ultrasound) ENLIGHT U.S. Phase II/III clinical trial for the indication of low risk, localized prostate cancer.

Greenleaf Health offers strategic guidance to healthcare sector clients whose activities are regulated by the Food and Drug Administration (FDA), and to those developing innovative solutions to pressing public health challenges. The Greenleaf Health team includes former leaders from the FDA, Capitol Hill, top global pharmaceutical companies, and the leading U.S. biotechnology trade organizations.

Marc Oczachowski, Chief Executive Officer of EDAP-TMS, stated, "Greenleaf Health joins the existing EDAP team of experts both internal and external, inclusive of specialized legal, regulatory, and Clinical Research Organization advisors, that has been working together to advance Ablatherm-HIFU through Phase III. As we progress through the final stages of our U.S. ENLIGHT clinical trial, this is an opportune time to bring Greenleaf on board. They will bring their strategic expertise to their role as advisor as we move forward in our Premarket Approval (PMA) filing to the U.S. FDA in the fourth quarter of 2012 and progressing through the regulatory process in the coming year."

Patrick Ronan, founder and President of Greenleaf Health, said, "The use of HIFU as a therapeutic option to treat localized prostate cancer shows great potential for the hundreds of thousands of men in the U.S. who are diagnosed each year with this disease. We look forward to working closely with the team at EDAP to provide strategic guidance through the FDA regulatory process for its Phase III submission."

About Greenleaf Health LLC

Greenleaf Health is a full service regulatory consulting firm that provides strategic guidance to companies regulated by the FDA and companies developing innovative solutions to pressing public health challenges around the globe and to a select group of healthcare sector clients, including pharmaceutical, biotechnology and medical device companies whose activities are regulated by the FDA. The Greenleaf team includes former leaders from FDA, Capitol Hill, top global pharmaceutical companies and the leading U.S. biotechnology trade organization. The wealth of experience allows the Greenleaf team to understand the broad health care industry, while appreciating the business challenges facing health care companies in a rapidly changing environment.

About EDAP TMS SA

EDAP TMS SA develops and markets Ablatherm®, the most advanced and clinically proven choice for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. 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. Approved in Europe as a treatment for prostate cancer, Ablatherm-HIFU (High Intensity Focused Ultrasound) is currently undergoing evaluation in a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA, the ENLIGHT U.S. clinical study. The Company also is developing this technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith® range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). 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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