

October 21, 2014

## EDAP Announces Sale of Focal One(R) HIFU Device to Nantes-Atlantis Urology Clinic in France

## Increasing Adoption of HIFU Focal in Leading French Robotic Prostate Cancer Centers

LYON, France, Oct. 21, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced the sale of a Focal One system to Nantes-Atlantis urology clinic, the top-ranked private prostate cancer clinic in France, and the country's only private clinic exclusively dedicated to urology.

Nantes-Atlantis Urology clinic is led by five renowned experts in urology, and offers the latest innovative technologies to patients suffering from urological diseases. The clinic performs more than 5,000 urological procedures per year, including more than 1,000 prostate cancer treatments. Nantes-Atlantis urology clinic has been successfully using the Focal One system on a mobile, per-treatment basis since early 2014, with 110 focal treatments performed year-to-date. By using the system on a per-treatment basis, Nantes-Atlantis' clinical team was convinced of the superiority of the focal HIFU technology and its revolutionary IRM/ultrasound fusing imaging approach, which led to its decision to purchase the device.

Dr. Georges Le Coguic, Chairman of Nantes-Atlantis urology clinic and Dr. Eric Potiron, urological surgeon and focal therapy expert, commented: "We are pleased to add the Focal One system, a revolutionary tool for prostate cancer, to our facility's suite of offerings. This is a real complement to our armamentarium of innovative technologies addressing prostate cancer. With Focal One, Atlantis-Nantes urology clinic will continue to be at the forefront of innovative therapeutic solutions in the treatment of prostate cancer."

Pierre Reboul, Director of EDAP's French Business Unit, commented: "We are very proud that our Focal One HIFU device is being used in the Nantes-Atlantis clinic, France's number one ranked private prostate cancer center. This system sale speaks to the momentum we are building for Focal One at key sites in Europe, following our sale to the leading public prostate cancer center in France: Institut Mutualiste Monsouris, Paris. We believe that the use of our Focal One technology at two of France's major prostate cancer centers is clear evidence that focal HIFU is becoming a must-have complement to robotic prostate surgery."

Reboul continued: "With the new reimbursement policies for HIFU treatment currently being rolled out in France, and our ability to offer a complete range of HIFU products to address prostate cancer management strategies, we are well positioned to address the estimated 10,000 prostate cancer patients per year that could benefit from HIFU technology, as published by the 'Haute Autorité de Santé' (French Health Authority)."

Marc Oczachowski, EDAP's Chief Executive Officer, concluded, "We are successfully expanding the footprint of our Focal One technology in Europe with strong support from leading prostate cancer centers. We will look to continue building on this adoption trend as we further develop our presence in the market through what we believe is an ideal solution to the growing demand for focal HIFU technologies in the treatment of prostate cancer."

## **About EDAP TMS SA**

EDAP TMS SA markets today Ablatherm<sup>®</sup> 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, Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in February 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. In March2013, the Company introduced a new innovative HIFU device, the Focal One<sup>®</sup> dedicated to focal therapy of prostate cancer. Focal One<sup>®</sup> 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 commercializes medical equipment (the Sonolith<sup>®</sup> range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <a href="http://www.hifu-planet.com">http://www.hifu-planet.com</a>.

## 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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