



August 5, 2014

EDAP Comments on FDA Panel Vote

Responds to Gastroenterology and Urology Devices Panel Vote on Ablatherm-HIFU for Treatment of Prostate Cancer

LYON, France, Aug. 5, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today provided comments on the recent Gastroenterology and Urology Devices Panel (GUDP) vote on the safety, efficacy and risk/benefit ratio for the use of its Ablatherm-HIFU device for treatment of low-risk, localized prostate cancer.

Chief Executive Officer Marc Oczachowski noted his disappointment and frustration that the panel has been unable to provide concrete guidance on a potential, acceptable approval path for a new device to treat prostate cancer. Mr. Oczachowski raised several key points that the Company believes should be considered under the FDA review process. He also highlighted EDAP's commitment to working closely with the FDA and its review team to identify a potential path to making Ablatherm-HIFU an available treatment choice for prostate cancer patients in the U.S.

Key points from Mr. Oczachowski included:

- Ablatherm-HIFU has a proven safety record through its approval and use in markets including Europe, Canada, Russia, Brazil, Mexico and South Korea;
- Ablatherm has treated more than 40,000 prostate cancer patients worldwide since its initial CE Mark approval in 2000;
- Recently the French Ministry of Health approved HIFU reimbursement for primary care patients at the same level as surgery;
- The Panel apparently agreed that the current approval path for new prostate cancer treatments is prohibitive and the likelihood that existing therapies, if evaluated on today's requirements, would be unlikely to qualify for a positive vote;

Mr. Oczachowski added, "We believe there is strong clinical evidence supporting the safety of our Ablatherm Integrated Imaging HIFU device. Indeed after 15 years of routine use, we see a growing adoption of the technology with approximately 4,000 treatments performed annually. To date, there have been no restrictions placed on the use of Ablatherm-HIFU from any of the numerous regulatory authorities under which it has been approved. If Ablatherm HIFU was dangerous or unsafe, it would not have survived more than five years in any market and would not be used by any urologist or would be forbidden by regulatory authorities around the world, this is not the case. We also believe that if it was not effective nor answering some patient needs, urologists around the world would have stopped using it."

Mr. Oczachowski concluded, "Based on the panel comments, we could interpret that applying today's standards to all available treatment options would result in no therapeutic options for low-risk prostate cancer patients in the U.S. Finally, we strongly believe that there are probably more risks in excluding a technology that has 15 year proven experience from the American patient choice than having it available in a controlled and monitored environment in the country, as it could result in an increasing HIFU medical tourism with the known risks associated."

About EDAP TMS SA

EDAP TMS SA markets today Ablatherm[®] 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 February 2013, the Company introduced a new innovative 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 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 statements00 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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