



March 31, 2015

## **EDAP Announces Sale of First Focal One(R) HIFU Device in North America**

### **Montreal Jewish General Hospital, Canada, Purchases Focal One HIFU Two Months After Health Canada Clearance**

LYON, France, March 31, 2015 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced the first sale of Focal One HIFU device to Jewish General Hospital, Montreal, Canada. This sale occurs only two months after the Company gained Health Canada's approval to market its Focal One HIFU device for focal treatment of prostate cancer.

The Montreal Jewish General Hospital is one of the leading institutions for the treatment of Prostate Cancer in the Eastern part of Canada. The Department of Uro-Oncology at Montreal Jewish General Hospital is headed by prominent urologist Franck Bladou, MD, also Professor of Surgery and Oncology at the prestigious McGill University.

Pr. Franck Bladou commented: "The concept of focal therapy for prostate cancer is a very promising treatment and appears to be the missing link between surveillance and robotic surgery for early stage prostate cancer patients. Focal One, together with its innovative MRI - ultrasound image fusing capabilities, is the only device capable of ablating the cancerous tissue within the prostate, using high-precision targeting, in a non-invasive way, sparing the rest of the prostate, and therefore minimizing the risk of side effect. The Jewish General Hospital is proud to be the first clinical site in the Americas to offer this therapeutic option to its patients."

Marc Oczachowski, EDAP's Chief Executive Officer, added, "We are very pleased to achieve this first sale of Focal One in Canada only two months after receiving marketing approval from Health Canada. This is an important validation of our innovative device dedicated to Focal therapy of prostate cancer from one of the leading hospitals in the region. Importantly, it allows us to further establish our HIFU technology in North America and offer this non-invasive focal solution to a larger number of prostate cancer patients in need."

Additionally, the Company announced that it plans to issue a press release announcing its financial results for the fourth quarter and twelve months ended December 31, 2014 on April 1, 2015 after the close of market. The Company previously announced that the press release would be issued during pre-market hours on April 2, 2015. The conference call to discuss fourth quarter and full-year 2014 results will take place as originally scheduled, at 8:30 a.m. ET on April 2, 2015. To participate in the call, please dial 1-888-348-6419 in the U.S., or 1-412-902-4235 internationally. The conference ID number is 10062222. A live webcast of the conference call will be available on the investor relations page of the Company's corporate website at [www.edap-tms.com](http://www.edap-tms.com).

### **About EDAP TMS SA**

EDAP TMS SA markets today Ablatherm<sup>®</sup> 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 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 for commercial distribution in Europe and some other countries including Mexico and Canada. EDAP TMS is currently pursuing a Direct De Novo 510(K) petition in parallel of a PMA for Ablatherm clearance by the U.S. FDA. The Company also markets an innovative robot-assisted 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 distributes medical equipment (the Sonolith<sup>®</sup> 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 treatment is in clinical trials, but not FDA-cleared or marketed in the United States.

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