

# EDAP TMS SA: EDAP Announces the Installation of a Third Focal One® HIFU Device in Brazil

September 27, 2018

HIFU Prostate Cancer Treatments Successfully Performed at Albert Einstein Hospital, Sao Paulo

LYON, France, September 27, 2018 -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced the installation of the third Focal One device in Brazil at the renowned Albert Einstein Center of Oncology,

Dr. Arie Carneiro MD, PhD, urologist at Albert Einstein Center of Oncology, commented: "In recent years we have experienced a great technological and information revolution. Patients are more sophisticated and well informed with often very different demands and priorities. Organ-sparing surgery is widely used for various neoplasms. The prostate has a particular anatomical location, hindering multiple surgical access and making partial surgery impossible. Prostate ablation with different energies has been proposed for focal treatment; however, safety and precision were the main limiting factors for the most of these approaches."

"Focal One certainly fills this gap by enabling accurate and safe treatment through advances in both resonance technology and robotic control. The Albert Einstein Hospital, as a reference cancer center, sought this technology in order to offer its patients an individualized approach, making available all the possibilities of treatment of localized prostate cancer, with the objective of achieving the best possible outcomes according to the characteristics of the patient and tumor. As a Latin America reference center, our research team will continue to produce scientific data to enhance the role of focal therapy and explore ways to further improve outcomes, as well as cost-effectiveness to the public and private health system."

Nicolas Poutrain, International Business Unit Director added: "With more than 70,000 new prostate cancer cases per year, Brazil is by far the fastest growing country for innovation and robotics in the management of localized prostate cancer in Latin America. The recent acquisition of Focal One by Albert Einstein Hospital in Sao Paulo, the leading private hospital in Brazil, is a significant milestone and achievement, as it will help EDAP and its local partner H. Strattner, to develop its strategy to offer HIFU to all main prostate cancer centers in Brazil."

Marc Oczachowski, Chief Executive Officer of EDAP TMS, concluded: "We are excited by the sale of our third Focal One device in Brazil, one of the largest prostate cancer markets in Latin America. We look forward to continuing our HIFU expansion in this region of the world."

#### **About EDAP TMS SA**

A recognized leader in the global therapeutic ultrasound market for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for urology using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in 2013 in Europe and in 2018 in the US as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA-cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. For more information on the Company, please visit <a href="http://www.edap-tms.com">http://www.edap-tms.com</a>, and us.hifu-prostate.com.

### **About Albert Einstein Hospital**

Albert Einstein Hospital Mission is to offer excellence in the field of healthcare, education, and social responsibility, as a way of highlighting the Jewish community's contribution to Brazilian society. Its vision is to be a leader and an innovator in medical and hospital care, a reference in managing knowledge, and recognized for its commitment to social responsibility. The organizational values such as Honesty, Truthfulness, Integrity, Diligence, Competence, and Fairness guide the institution's activities and employees. For the seventh year in a row, the Einstein was ranked by the América Economía Intelligence Magazine as the best hospital in Latin America.

## **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.

### **Company Contact**

Blandine Confort Investor Relations / Legal Affairs EDAP TMS SA +33 4 72 15 31 50 bconfort@edap-tms.com

Investor Contact

Jeremy Feffer LifeSci Advisors, LLC 212-915-2568 jeremy@lifesciadvisors.com



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