Edap Tms: EDAP Announces Positive Outcome from CPT Panel for HIFU Reimbursement in the U.S.

June 10, 2019

- **AMA allocates a new Category 1 CPT code for High Intensity Focused Ultrasound (HIFU)**
- **Definitive CPT code will cover the transrectal ablation of malignant prostate tissue with HIFU including ultrasound guidance**

LYON, France, June 10, 2019 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in therapeutic ultrasound, today announced that the American Medical Association's ("AMA") CPT® Editorial Panel, at its May 2019 meeting, accepted EDAP's application to establish a new Category 1 CPT code that will facilitate reimbursement for the ablation of malignant prostate tissue with HIFU technology. The CPT code description selected by the Panel is "*Ablation of malignant prostate tissue, transrectal, with high intensity focused ultrasound (HIFU) including ultrasound guidance."* The code will be included in the next CPT® Codebook and be effective on January 1, 2021.

Marc Oczachowski, EDAP's Chief Executive Officer, said, "The AMA's acceptance of our request for a Category 1 CPT code is a significant milestone for EDAP in the reimbursement process of HIFU in the U.S. and a major step forward in the recognition of Focal One®, which combines HIFU with proprietary ultrasound guidance technology, as a highly differentiated tool for the targeted ablation of prostate tissue. Additionally, we believe the specific reference to malignant tissue, transrectal approach and ultrasound guidance in the code description is clearly favorable to EDAP and its unique and latest HIFU device generation, the Focal One."

"Importantly, this Category 1 CPT code now gives us line-of-sight to definitive reimbursement and, we believe, will have a positive impact on both sales and utilization going forward as it sets and gives a long term guaranty on the HIFU use and adoption to all of our prospects and leads. We look forward to specific reimbursement details in mid-2020, while we further grow our sales pipeline in the U.S. and other key territories," Mr. Oczachowski concluded.

The American Urology Association ("AUA") and the American Association of Clinical Urologists ("AACU") both supported the application and also participated in the AMA Panel to discuss creation of the code for ablation of malignant prostate tissue by HIFU.

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 http://www.edap-tms.com, and us.hifu-prostate.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 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.

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