EDAP Announces Final U.S. 2021 Reimbursement Rules for High Intensity Focused Ultrasound (HIFU)

December 9, 2020

- Final rules establish, for the first time, a Category 1 CPT code and reimbursement to physicians performing ablation of malignant prostate tissue with HIFU in the US
- Physician reimbursement for HIFU approximately 30% higher than cryotherapy and brachytherapy
- Hospital reimbursement for HIFU up approximately 6% versus 2020 levels
- Final reimbursement rule confirms proposed rule released on August 12

LYON, France, December 9, 2020 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy based therapies, announced today that the U.S. Centers for Medicare and Medicaid Services (CMS) has issued its final rules establishing, for the first time, a Category 1 CPT code which facilitates reimbursement for the ablation of malignant prostate tissue with HIFU technology, effective January 1, 2021.

On the Hospital Payment side, the final rule maintains the HIFU procedure in the Level 5 Urology Ambulatory Payment Classification (APC) in 2021. This translates into a payment for a hospital performing a HIFU procedure on a Medicare patient of around $4,500 as a national average, adjusted locally based on the wage index. This represents an increase of $256, or 6%, from the payment hospitals receive from Medicare for a HIFU procedure in 2020.

In the Physician Fee Schedule final rule, CMS has established for the first time a payment to physicians performing a HIFU procedure in the US. In the final rule, CMS has set a total Relative Value Units (RVUs) for a physician performing a HIFU procedure at 29.09. This translates to an average payment of $943 for a urologist performing a HIFU procedure on a Medicare patient in a facility setting. As a reference, a comparable established minimally invasive therapy for prostate cancer, cryotherapy, yields 22.72 RVUs, which translates to $736 for the urologist under the same setting and patient conditions. A radical prostatectomy would grant the urologist 34.73 RVUs, which translates to a Medicare payment of $1,125, or 42.74 RVUs and $1,385 if performed laparoscopically.

Marc Oczachowski, Chairman and Chief Executive Officer of EDAP, commented: "We are very pleased that CMS, through the establishment of physician reimbursement, further validates the value of HIFU in treating prostate diseases. The process was finalized in a timely manner and has positioned the therapy very well among the existing treatment options such as cryosurgery, brachytherapy and surgery. We anticipate that this incremental revenue stream will also be a significant driver to further adoption of Focal One as physicians and hospitals seek to differentiate themselves by offering this cutting edge, non-invasive treatment option."

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies 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 Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device,EDAP TMS is now the only company offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the 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 us.hifu-prostate.com.

Forward-Looking Statements

In addition to historical information, this press release contains 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, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. 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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Source: EDAP TMS S.A.