EDAP Announces Focal One® HIFU Reimbursement Raised to Urology APC Level 6 Under CMS Outpatient Prospective Payment System (OPPS) Final Rule for CY23

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Final rule significantly raises Medicare reimbursement to U.S. hospitals performing a Focal One HIFU prostate ablation procedure

LYON, France, November 1, 2022 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic therapeutic ultrasound, today announced that the U.S. Centers for Medicare and Medicaid Services (CMS) has released its final outpatient prospective payment system (OPPS) reimbursement rule for calendar year 2023 (CY23), which becomes effective on January 1st.

For a hospital performing a Focal One HIFU prostate ablation on an outpatient basis, the final rule increases the reimbursement level to an Ambulatory Payment Classification (APC) level 6, as compared to APC level 5 currently. This will increase reimbursement to a hospital performing a HIFU procedure on a Medicare patient to $8,558 per procedure as compared to $4,506 currently as a national average, adjusted locally based on the wage index. This represents an increase of more than 90% over the current reimbursement level.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, stated, "We are very pleased that CMS recognizes the true value of HIFU in this important indication, as reflected in the significant increase in reimbursement that will go into effect on January 1st. We view this as a very positive step forward for the prostate cancer patients who can benefit from this novel therapy."

Ryan Rhodes, Chief Executive Officer of EDAP US, stated, "This final rule change is a significant development in achieving appropriate reimbursement for facilities offering their patients a precise treatment with Focal One HIFU. We expect that this change will serve as a major catalyst towards accelerating broader access and adoption of Focal One across the U.S."

As previously noted, the increase to APC level 6 has positive implications for patients beyond Medicare since many commercial payors have begun to cover focal HIFU for their members. Commercial payment and access policies are influenced by Medicare policy and reimbursement decisions.

EDAP management will provide additional commentary around the impact of the positive reimbursement change during its upcoming third quarter 2022 results conference call, which will be held in mid-November.

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, us.hifu-prostate.com and www.focalone.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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