



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

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Proposed rule, if adopted for CY23, would increase Medicare Payment for a Focal One HIFU procedure completed on an outpatient basis at a hospital

LYON, France, July 18, 2022 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, today announced that the U.S. Centers for Medicare and Medicaid Services (CMS) has released its proposed outpatient prospective payment system (OPPS) reimbursement rule for calendar year 2023 (CY23).

For a hospital performing a Focal One HIFU prostate ablation on an outpatient basis, the proposed rule would increase the reimbursement level to an Ambulatory Payment Classification (APC) level 6, as compared to APC level 5 currently. This would result in an increase in reimbursement to a hospital performing a HIFU (High-Intensity Focused Ultrasound) procedure on a Medicare patient to \$8,711 per procedure as a national average, adjusted locally based on the wage index, as compared to \$4,506 currently as a national average, adjusted locally based on the wage index.

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.

Ryan Rhodes, Chief Executive Officer of EDAP US, stated, "This proposed rule reflects the realization of the appropriate value of HIFU within the prostate care continuum, particularly relative to more invasive treatments like radical surgery or radiation. If the final rule maintains the increase in reimbursement levels being proposed here, we believe this would be a significant catalyst to accelerating access for facilities and their patients to the benefits of focal HIFU."

Comments on the proposed rule are due by September 30, and the final rule is anticipated in November. The policies and payment rates in the final rule will generally take effect Jan. 1, 2023.

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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