EDAP Receives HIFU Reimbursement for Prostate Cancer in France

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- Focal One Robotic HIFU procedure now covered under France's national universal health system
- Reimbursement milestone allows increased patient access to Focal One Robotic HIFU

AUSTIN, Texas, September 8, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, announced today that the French Ministry of Health has awarded reimbursement for High Intensity Focused Ultrasound (HIFU) procedure for the treatment of prostate cancer in France. Reimbursement in France will specifically cover use of the Focal One Robotic HIFU procedure for eligible patients as a primary treatment of localized prostate cancer as well as a salvage treatment option following radiotherapy.

"Securing reimbursement for Focal One in France represents an important commercial milestone for our company, allowing a significant number of prostate cancer patients access to an effective, non-invasive, treatment for managing their prostate cancer. Importantly, the positive results from the groundbreaking HIFI Study provided the critical scientific evidence to help secure reimbursement for Focal One," said Ryan Rhodes, Chief Executive Officer. "As one of the largest healthcare markets in Europe, we also believe that securing reimbursement in France is likely to accelerate reimbursement for Focal One Robotic HIFU in additional European countries. Over time, we anticipate additional emerging clinical evidence supporting the use of focal therapy in the management of prostate cancer will drive further adoption of Focal One. In addition to the HIFI study, we believe the Level 1 evidence from the FARP Study, which was recently presented at this year's American Urological Association Annual Meeting, will also help accelerate demand for our leading Focal One platform, as a growing number of urologists realize the benefits of HIFU over radical treatment options such as surgery or radiation."

This final step in the reimbursement pathway follows the positive favorable opinion issued in December 2023 by the French National Authority for Health (HAS) to include HIFU as a procedure covered under the national universal health system, Social Security ("Sécurité Sociale") following the completion and analysis of the HIFI Study sponsored by the French Urology Association. Coverage became effective on September 1, 2025, and reimbursement details will become available in the near future.

For more information about the results from HIFI Study, please visit hifistudy.com.

About EDAP TMS SA

A recognized leader in robotic energy-based therapies, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various conditions using ultrasound technology. By combining the latest technologies in imaging, robotics and precise non-invasive energy delivery, EDAP introduced the Focal One® in Europe and in the U.S. as the leading prostate focal therapy controlled by urologists with the potential to expand to multiple indications beyond prostate cancer. For more information on the Company, please visit https://focalone.com/

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 (the "Securities Act") or Section 21E of the U.S. Securities Exchange Act of 1934, which may be identified by words such as "believe," "can," "contemplate," "could," "plan," "intend," "is designed to," "may," "might," "potential," "objective," "target," "project," "predict," "forecast," "ambition," "guideline," "should," "will," "estimate," "expect" and "anticipate," or the negative of these and similar expressions, which reflect our views about future events and financial performance. Such statements include our expectations to enter into a credit facility with EIB, the size thereof, the timing thereof and the use of proceeds from such credit facility. 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 and distribution divisions, as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics like the COVID 19 pandemic, or other public health crises, and their related impact on our business operations, including their impacts across our businesses or demand for our devices and services. Other factors that may cause such a difference may also 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.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any

obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

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