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AUSTIN, Texas, November 20, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for new ultrasound imaging and workflow enhancements to the Focal One High Intensity Focused Ultrasound (HIFU) system, further strengthening the company's market leadership in robotic focal therapy for prostate cancer.

The 510(k) clearance introduces advanced ultrasound imaging, streamlined treatment planning, and an optimized user-interface to the Focal One i launched earlier this year. The next generation ultrasound imaging engine provides real-time visualization and supports the potential development of AI-driven algorithms designed to assist surgeons with tissue ablation visualization and treatment evaluation.

"We are proud to receive this new FDA clearance, which further enhances the capabilities of the new Focal One i and represents another important technical milestone in Focal One's product roadmap," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "This achievement demonstrates our team's continued commitment to innovation and reinforces Focal One's global leadership in focal therapy."

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 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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