EDAP To Launch New Focal One® i Robotic HIFU system at the Upcoming 120th American Urological Association (AUA) Annual Meeting

Apr 24, 2025

- Focal One i expands HIFUsion® patient-specific imaging compatibility to include PSMA PET, ExactVu™ Micro-Ultrasound, along with AI-driven and intelligent algorithms including Unfold AI™ and OnQ™ Prostate
- Focal One i extends HIFUsion capabilities to integrate Koelis® 3D biopsy maps and DynaCAD Urology datasets
- Focal One i system will enable future capabilities including treatment streaming and recording, remote collaborative procedures and expanded clinical indications

AUSTIN, Texas, April 24, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, announced the launch of the new Focal One i system at the upcoming 120th American Urological Association (AUA) Annual Meeting being held in Las Vegas, Nevada from April 26-29, 2025.

The Focal One i system incorporates important new features and enhanced capabilities including:

- Expanded HIFUsion compatibility including Prostate-Specific Membrane Antigen (PSMA) PET scans, ExactVu Micro-Ultrasound, Unfold AI® and OnQ Prostate®, as well as extended capabilities for Koelis 3D biopsy maps and DynaCAD Urology datasets
- Streamlined HIFUsion and treatment workflows with guided, step-by-step procedures designed to improve efficiency
- Onboard Video Libraries to facilitate sharing standard techniques and clinical best practices
- Integrated ability to stream and record Focal One i treatments as well as enabling remote proctoring and remote collaborative procedures

"The new features and design of the Focal One i system are based directly on the feedback from our customers, as well as anticipating the future needs of surgeons performing focal therapy. Voice of Customer feedback is clear that Focal One surgeons want to incorporate the latest diagnostic imaging modalities like PSMA PET and emerging AI- driven and intelligent algorithms to further personalize Focal One Robotic HIFU procedures," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "In addition, we believe Focal One's digital interface and fully robotic HIFU energy delivery design is uniquely suited to enable remote proctoring and remote collaborative procedures. Cleveland Clinic's successful achievement of the world's first remote transatlantic Focal One Robotic HIFU treatment from Ohio to Abu Dhabi serves as the first step in continued innovations that will allow Focal One surgeon experts to connect remotely and share their expertise. We also believe the Focal One i will allow more efficient and effective training and mentoring of surgeons while further broadening patient access to expert care."

AUA attendees are invited to visit the Focal One booth #1419 to experience a hands-on demonstration of the Focal One i system and explore the new features, system design, and future capabilities that demonstrate Focal One's continued commitment to innovation and reinforce its 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 TMS 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.

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