



EDAP Announces Significant Presence of Focal One® at the Upcoming 120th American Urological Association (AUA) Annual Meeting

Apr 22, 2025

- Activities to include expert-led demonstrations, semi-live Focal One procedures and hands-on simulations
- Final results of randomized clinical trial (FARP Study) comparing ultrasound-based focal ablation versus radical prostatectomy as a first-line treatment for prostate cancer
- Presentation on the first ever remote transatlantic Focal One Robotic HIFU procedure will be given by Ruben Olivares, MD, Urologic Surgeon at the Cleveland Clinic, at the AUA session of the Engineering & Urology Society
- Notable increase in the number of scientific presentations on focal therapy and ablation in the management of prostate cancer
- Focal One Robotic HIFU Masterclass will be held at the Keck School of Medicine of the University of Southern California on April 24-25th, prior to AUA Annual Meeting

AUSTIN, Texas, April 22, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced that Focal One will have its largest presence ever at the upcoming 120th American Urological Association (AUA) Annual Meeting.

“This year’s AUA meeting promises to be the most significant scientific meeting to date highlighting the growing acceptance and utilization of the Focal One Robotic HIFU platform by the global urology community,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “We will have our largest presence ever at this year’s meeting, enabling us to offer numerous hands-on Focal One simulations, live demonstrations by some of the leading experts in focal therapy, as well as featuring multiple semi-live procedures. Leading into the AUA, the first ever Focal One Robotic HIFU Masterclass will be held at the Keck School of Medicine of USC in Los Angeles, which will be led by world-renown expert faculty and will feature several live Focal One procedures, along with offering hands-on Focal One simulations for attendees.

“We also anticipate a growing number of presentations focused exclusively on robotic HIFU technology at this year’s AUA Annual Meeting, including the much-anticipated final results from the FARP study, which is the first randomized, controlled clinical trial designed to generate level-1 evidence evaluating focal therapy using ultrasound ablative energy versus robotic prostatectomy as a first-line treatment for early-stage prostate cancer. I am also pleased to note that Dr. Ruben Olivares will be making a presentation highlighting the first ever remote transatlantic Focal One Robotic HIFU procedure at the upcoming AUA Annual meeting. We are obviously excited about this event which underscores Focal One’s highly advanced technology and remote capabilities.”

Focal One Highlights at AUA2025

- Presentation of the final results from the first randomized control trial (“FARP Study”) ever completed that compares focal therapy to the standard of care treatment (robotic prostatectomy). The presentation is titled “Final, three-year oncological results of a randomized clinical trial FARP comparing focal ablation and radical prostatectomy in patients with unilateral clinically significant prostate cancer” and is scheduled to be presented in person by the lead investigator, Eduard Baco from Oslo University Hospital in Norway as part of a podium presentation session titled “Prostate Cancer: Localized: Ablative Therapy II” on Sunday, April 27, 2025, at 3:30 PM PT. This first much-anticipated level-1 evidence trial will be instrumental in providing the scientific argument in support of focal ablation with Focal One shortly after the publication of the HIFI Study, the largest prospective comparative study already providing strong support in favor of Focal One’s ability to provide comparable cancer control and superior urinary and erectile function preservation as compared to surgery.
- Ruben Olivares, MD, Urologic Surgeon at the Cleveland Clinic, will be presenting the successful experience of the very first remote transatlantic Focal One Robotic HIFU procedure in a presentation titled “Telesurgery for Focal Therapy: The First Transcontinental Clinical Application” on Monday, April 28, 2025, at 9:16 AM PT as part of the session of the Engineering & Urology Society (EUS). A link first announcing this procedure can be found [here](#), as well as a link to the [video of the procedure](#).
- EDAP to host the first ever Robotic Focal HIFU Masterclass at USC in Los Angeles on April 24-25th, two days ahead of the AUA Annual Meeting. In addition to the 10+ renowned faculty from some of the highest-ranked institutions in the United States and Europe, more than 80 urologists from the U.S. and around the world have registered for this unique and exciting event. The program will include lectures, hands-on Focal One simulations, and three live Focal One procedures.

Sebastien Crouzet, MD, PhD, Professor and Associate Chief of Urology of Lyon University Hospital will be giving a Keynote Lecture titled "Lessons Learned from 3,000 Focal One Procedures".

- Focal One activities at AUA are expected to be the largest in the company's history with hands-on simulations, expert-led demonstrations, semi-live Focal One procedures, and breakout meetings with key scientific thought leaders.
- This year's scientific program features a significant number of scientific presentations on focal therapy and ablation in this year's official program, including multiple plenary sessions and podium presentations, pointing towards the growing utilization of robotic HIFU technology in the management of prostate cancer.

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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