



EDAP Announces Positive Results from the FARP Randomized Controlled Trial Presented at the American Urological Association (AUA) Annual Meeting

Apr 29, 2025

- Final 3-year outcome of Focal Ablation versus Radical Prostatectomy (FARP) Randomized Controlled Trial (RCT) presented at 120th AUA Annual Meeting on Sunday, April 27, 2025.
- Study achieved its primary endpoint and demonstrated that the rate of treatment failure in the Focal Ablation (FA) group is non-inferior to that in the Radical Prostatectomy (RP) group at the final 36-month follow-up.

AUSTIN, Texas, April 29, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, announced the positive final results of the Focal Ablation Versus Radical Prostatectomy (FARP) Study, the first randomized controlled trial completed comparing ultrasound energy-based focal ablation versus Robotic Prostatectomy. The study achieved its primary endpoint and demonstrated that the rate of treatment failure in the Focal Ablation (FA) group is non-inferior to that in the Radical Prostatectomy (RP) group at the final 36-month follow-up.

"The purpose of this study was to generate scientific Level 1 evidence comparing focal therapy for the treatment of clinically-significant localized prostate cancer versus robotic prostatectomy," said Eduard Baco, MD, PhD, Associate Professor at the Department of Cancer Surgery at the Oslo University Hospital and Principal Investigator of the FARP Study. "Our final 3-year results met the primary endpoint of showing non-inferiority between the two arms of the trial, with the results showing a significantly lower rate of treatment failure in the focal ablation arm compared to the robotic prostatectomy arm. The findings from this randomized controlled trial provide significant additional evidence that support the use of focal ablation with ultrasound energy for the management of organ-localized prostate cancer, in particular HIFU."

FARP Trial Results

- A total of 213 patients were enrolled in the study; 107 were randomized to FA and 106 to RP.
- 25% (26/106) of the patients in the RP arm refused surgery and crossed-over to the FA arm.
- The two arms were equivalent in terms of mean age (64 vs. 66 years, $p=0.3$), PSA (8.6 vs. 8.5 ng/ml, $p=0.9$), index tumor diameter on MRI (14.5 vs. 15.5 mm, $p=0.2$), prostate volume (41.3 vs. 41.7 ml, $p=0.9$) and Gleason Grade Group on biopsy.
- All included patients were evaluated following an intention-to-treat (ITT) analysis.
- The proportion of treatment failure was 5.6% in the FA arm (6/107; 95% CI [3 – 13]) vs 7.9% in the RP arm (8/101, 95% CI [5 - 15]), resulting in a statistical difference of 2.3% (95% CI [-4.9 – 9.9]) in favor of Focal Ablation.

"The positive results from the FARP randomized controlled trial further validate the role of robotic focal ablation with ultrasound energy in the management of prostate cancer," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "Focal One Robotic HIFU was used for the vast majority of the patients treated with focal ablation in this study. This demonstrates Focal One's leadership position in the rapidly growing treatment category of focal therapy for prostate cancer. We anticipate that the positive data from the FARP trial, once published, combined with the recent publication of the HIFI Study, the largest prospective, comparative study ever conducted demonstrating Focal One's ability to provide comparable cancer control and superior urinary and erectile function preservation as compared to surgery, will be instrumental in further accelerating adoption of Focal One Robotic HIFU."

A link to the FARP Study abstract can be found [here](#).

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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