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EDAP Announces Positive Final Results from the HIFI Study Comparing Outcomes of Focal One® HIFU Versus Radical Prostatectomy During Plenary Session at the 119th American Urological Association (AUA) Annual Meeting

May 06, 2024

Final results demonstrate a significantly higher salvage treatment free survival rate (STFS) at 30 months of 89.6% in the HIFU-treated arm versus 86.2% in patients who underwent radical prostatectomy (RP)

Functional evaluation criteria show better results with respect to urinary continence and erectile function in patients receiving HIFU therapy versus patients receiving RP

Final study results were presented during a plenary session of the AUA focused on paradigm-shifting and practice-changing clinical trials in urology

HIFI Study is the largest clinical study ever conducted evaluating treatment outcomes with Focal One robotic HIFU, enrolling a total of 3,328 prospective patients, including 1,967 consecutive HIFU patients and 1,361 RP patients across 46 centers

LYON, France, May 6, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, announced a recent presentation highlighting the positive, final results from a large, prospective, multicenter, non-inferiority study, the HIFI Study, comparing Focal One® high intensity focused ultrasound (HIFU) versus radical prostatectomy (RP) at the 119th American Urological Association Annual Meeting (AUA 2024), which took place from May 3-6, 2024, in San Antonio, Texas, USA. Professor Pascal Rischmann of Rangueil University Hospital in Toulouse, France, and lead investigator of the HIFI Study, highlighted the final results from the study during an oral presentation at the AUA plenary session, "Paradigm-shifting, Practice-changing Clinical Trials in Urology".

HIFI is the first prospective, multi-center, investigator-sponsored study comparing robotic HIFU to RP in the management of prostate cancer. The study, which ran from April 2015 through March 2022, compared Focal One HIFU versus RP as a first line treatment for patients with localized prostate cancer (grade groups <3). A total of 3,328 patients from 46 treatment centers were included: 1,967 consecutive patients were treated with EDAP's robotic HIFU technologies, where Focal One was used for 90% of the patients. 1,361 patients underwent radical prostatectomy surgery. All patients were followed for 30 months.

Select data highlights:

- At 30 months, the STFS was higher in the HIFU arm (89.6%) compared with RP arm (86.2%)
- The propensity score-adjusted result is similar to the univariate result (HR=0.75 [0.55-1.03], p=0.076). After adjustment on different variables (Age, BMI, ASA score, Grade Group, prostate volume, PSA) the results are similar to the univariate analysis: the risk of salvage treatment is lower in the HIFU arm compared to RP
- International Continence Society (ICS) score, a measure of urinary incontinence, was significantly lower after HIFU for 3 of the 4 questions
- Urinary Symptom Profile (USP) showed a significantly lower stress incontinence score for patients after HIFU than RP (0 vs 1, p<0.001)
- International Index of Erectile Function-5 (IIEF-5), a well validated measurement of erectile function, decreased significantly less after HIFU than after RP in patients 69 and older with a score of 15 or higher at baseline (median Δ = -8 vs -13 p < 0.001)
- Post-procedural benefits of HIFU on both erectile function and urinary continence were demonstrated despite patients in the HIFU-treated group being an average of 9.6 years older (median age was 74.7 years for HIFU vs 65.1 years for RP, p<0.0001)

"The final results from the HIFI Study clearly demonstrate that treatment with robotic HIFU for the management of localized prostate cancer is at least as effective as radical prostatectomy, but with added potential for improved safety outcomes with respect to urinary continence and sexual function," said Professor Pascal Rischmann. "It is increasingly evident that the application of robotic HIFU has growing relevance in the management of localized disease, and these final results from the HIFI Study provide conclusive evidence in support of this technology as a safe, effective, and less invasive approach to remove cancerous tissue from the prostate."

"As the largest and most rigorous clinical study ever conducted to evaluate treatment outcomes with Focal One robotic HIFU, the final results from the HIFI Study provide clear and compelling evidence that supports the use of robotic HIFU as an important and growing treatment option for the management of prostate cancer," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "We believe the final results from the HIFI study not only represent an important clinical milestone for EDAP, but also serves as a further validation of Focal One as the best focal therapy of choice for the management of men diagnosed with early-stage prostate cancer. EDAP remains well positioned to deliver this technology as we continue to build world-class treatment programs for urologists centered around our leading Focal One robotic HIFU technology platform."

About the American Urological Association (AUA) Annual Meeting

The [AUA Annual Meeting](#) is the world's foremost meeting of urologists. It attracts more than 11,000 practicing physicians and healthcare professionals to the largest gathering of urological professionals worldwide. With over 300 technical exhibitors, more than 90 educational courses, and over 2,000 accepted abstracts, it delivers the latest in urologic medicine – providing needed tools to healthcare professionals as they continue to improve patient care. Additional information on the meeting can be found at <https://annual2024summit.com/aua/index.php>

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device, EDAP TMS is now the only company offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <http://www.edap-tms.com>, us.hifu-prostate.com and www.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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