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Bringing New Horizons to Therapy

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

Apr 23, 2024

LYON, France, April 23, 2024 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, announced that final results from the HIFI Study, the largest clinical trial ever conducted comparing EDAP's Focal One robotic high intensity focused ultrasound (HIFU) versus radical prostatectomy (RP) for the treatment of prostate cancer, will be presented during a plenary session at the 119th American Urological Association Annual Meeting (AUA 2024), which is taking place from May 3-6, 2024, in San Antonio, Texas, USA.

Presentation details:

Plenary Session: **P2s: Paradigm-shifting, Practice-changing Clinical Trials in Urology: HIFI trial: HIFU vs Radical prostatectomy for localized Prostate cancer in 3328 cases. Final results.**

Date/Time: Friday, May 3, 2024; 11:11 AM CDT

Location: Stars at Night Ballroom (Henry B. Gonzalez Convention Center)

Presenter/Speaker: Professor Pascal Rischmann

About the American Urological Association (AUA) Annual Meeting

The [AUA Annual Meeting](https://annual2024summit.com/aua/index.php) 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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