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Bringing New Horizons to Therapy

EDAP Announces Preliminary Fourth Quarter Record Focal One® System Sales and Placements

Jan 08, 2024

Company reports preliminary placement results of twelve Focal One Systems, inclusive of ten capital sales

LYON, France, January 8, 2024 - EDAP TMS SA (Nasdaq: EDAP), ("EDAP"), the global leader in robotic energy-based therapies, announced today preliminary Focal One placement results for the fourth quarter of calendar year 2023. The Company experienced robust demand for its Focal One robotic HIFU technology, placing twelve Focal One systems, inclusive of ten capital sales. Additionally, it was a record quarter for sales of ExactVu™ Micro-Ultrasound systems used for prostate biopsy. The breadth of these new Focal One and ExactVu placements continues to be strong, with growing interest amongst both academic medical centers and community hospitals.

"Our Focal One commercial team continues to gain significant momentum as reflected by our record-setting number of capital sales as well as overall system placements in the fourth quarter of 2023," said Ryan Rhodes, Chief Executive Officer of EDAP. "Utilizing our state-of-the-art robotic technology platform, a growing number of urologists can now offer their patients a non-invasive, tissue-sparing treatment option that provides excellent oncologic outcomes with the opportunity for preserving patient quality of life. Looking ahead, we believe Focal One is quickly becoming a necessary solution in the management of prostate cancer, and our team is leading the effort to help urology practices establish world-class treatment programs with our Focal One platform."

The above information is preliminary and subject to completion of quarter-end financial reporting processes and reviews. EDAP expects to release final fourth quarter financial results in March.

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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