

EDAP Announces Reimbursement Approval in Switzerland for the Use of High-Intensity Focused Ultrasound (HIFU) in the Treatment of Prostate Cancer

Jul 26, 2023

LYON, France, July 26, 2023 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, today announced that it has received reimbursement approval in Switzerland for the use of High-Intensity Focused Ultrasound (HIFU) in the treatment of prostate cancer. This reimbursement took effect on July 1, 2023.

"Receipt of appropriate reimbursement from the Swiss healthcare authorities is another acknowledgment of the growing, worldwide acceptance of HIFU as an effective treatment option for men diagnosed with prostate cancer," remarked Ryan Rhodes, Chief Executive Officer of EDAP TMS. "We expect this change will result in a growing awareness of HIFU as an important treatment option in Switzerland, which should lead to more patient demand for Focal One® Robotic HIFU procedures. Additionally, increasing access to Focal One in Switzerland may signal greater momentum in Europe for hospitals and payors to support HIFU as an integral part of the comprehensive management of prostate cancer."

"Thanks to the new reimbursement of HIFU in Switzerland, Swiss patients with prostate cancer now have greater access to a precise treatment option with low side effects," said Dr. Daniel Eberli, Professor of Urology, Director of Department of Urology at the University Hospital Zurich who led the initiative to secure reimbursement for HIFU in Switzerland.

Switzerland has many hospitals ranked amongst the best 250 in the world according to Newsweek's "The World's Best Hospitals 2023". Included in this list is the University of Zurich, the leading innovation center for HIFU in the country and a Focal One site. The University of Zurich is also a member of the League of European Research Universities, placing it among Europe's most prestigious research institutions. Switzerland is also a member of the DACH market region (including Germany, Austria and Switzerland) with over 100 million total inhabitants.

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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