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Bringing New Horizons to Therapy

## **EDAP Announces Positive Opinion for Reimbursement from the French National Authority for Health (HAS) for HIFU treatment of Prostate Cancer**

Dec 12, 2023

*Represents Key Milestone Toward Universal Coverage for Focal One HIFU in France*

LYON, France, December 12, 2023 - EDAP TMS SA (Nasdaq: EDAP), ("EDAP"), the global leader in robotic energy-based therapies, today announced that the French National Authority for Health ("HAS") released a favorable recommendation for the reimbursement of high-intensity focused ultrasound (HIFU) therapy in the treatment of prostate cancer. The positive opinion from HAS is an important milestone along the regulatory pathway of securing final reimbursement in France.

"We are pleased to receive this positive opinion from the HAS, which we believe reflects the outstanding safety and favorable clinical outcomes from use of Focal One Robotic HIFU in the HIFI study that included more than 3,000 prostate cancer patients," said Ryan Rhodes, Chief Executive Officer of EDAP. "Today's decision brings us one step closer toward securing reimbursement coverage from the French Social Security authorities, as we seek to expand treatment options for physicians and their patients with our leading Focal One HIFU technology platform."

Following the completion and analysis of the HIFI study sponsored by the French Urology Association and submitted to the HAS, a positive favorable opinion was issued to include HIFU as a procedure covered under the national universal health, Social Security system ("Sécurité Sociale"). More specially, the favorable opinion relates to HIFU as a primary treatment of intermediate risk localized prostate cancer as well as a salvage option after failed radiotherapy. Based on this positive opinion from the HAS, the French Social Security authorities can now use this recommendation for including HIFU procedures in its next cycle to determine the procedure's reimbursement rate and the timing for when such reimbursement would go into effect.

### **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](http://us.hifu-prostate.com) and [www.focalone.com](http://www.focalone.com).

### **About HAS**

An independent, scientific public authority, the Haute Autorité de Santé (HAS) aims to develop quality in the healthcare, social and medico-social fields, for the benefit of individuals. It works alongside public authorities, helping them to make informed decisions, with professionals to optimize their practices and organizations, and for the benefit of users, empowering them to make their own choices. It was created by the French Health Insurance Act of August 13, 2004.

### **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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