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Bringing New Horizons to Therapy

EDAP Announces Regulatory Clearance of ExactVu Micro-Ultrasound in Japan

April 6, 2023

Allows for market launch of the only micro-ultrasound platform for precision prostate biopsies

LYON, France, April 6, 2023 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), a global leader in robotic energy-based therapies, today provided a regulatory and clinical update. The Company has received approval from the Pharmaceutical and Medical Devices Agency ("PMDA") for the commercialization of the ExactVu™ micro-ultrasound biopsy platform in Japan.

"We are pleased to announce the approval of the ExactVu system in Japan," said Marc Oczachowski, Chief Executive Officer and Chairman of the Board of EDAP TMS. "The Japanese market is the second largest market for advanced medical device technology in the world, and prostate cancer is the most common cancer diagnosis in Japanese men. Each year, there are over 100,000 newly diagnosed cases of prostate cancer. Our established commercial team in Japan is well positioned to engage clinical sites to offer their patients precise prostate biopsies utilizing this groundbreaking technology."

ExactVu is a micro-ultrasound platform that provides the most practical solution as a new tool for urologists or radiologists to perform targeted biopsies within a standard urological workflow. The unique 29MHz frequency allows practitioners to visualize details unseen before in any prostate ultrasound image, detect suspicious areas in real-time and take a biopsy sample as representative of the level of aggressiveness of the cancer. ExactVu™ is already available for sale in the European Union (CE Mark), the United States (FDA 510(k) clearance), and in Canada (Health Canada license).

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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