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Bringing New Horizons to Therapy

EDAP TMS SA : John Wayne Cancer Institute First US Medical Center to Acquire EDAP's Breakthrough Focal One® Technology for Prostate Tissue Ablation

January 3, 2019

Focal One System Enhances Precision Tissue Ablation, Reduces Side Effects for Prostate Cancer Patients

LYON, France -- January 3, 2019 -EDAP TMS SA (Nasdaq: EDAP) today announced that the John Wayne Cancer Institute (JWCI) at the Providence Saint John's Health Center in Santa Monica, CA is the first medical center in the U.S. to offer focal therapy to patients with localized prostate cancer using Focal One, the most advanced technology available for delivering high intensity focused ultrasound (HIFU) to target and ablate diseased tissue.

While the capital equipment sales cycle within the hospital industry can be lengthy, this initial sale into the U.S. market comes just six months after Focal One received 510(k) clearance from the FDA in June 2018.

"Our formal entry into the U.S. market with Focal One represents a transformational achievement for our company and, we believe, reflects the significant advantages of our next-generation HIFU technology versus more traditional prostate cancer treatment modalities," said Marc Oczachowski, Chief Executive Officer of EDAP. "Going forward, we intend to maintain this momentum by advancing discussions with other leading healthcare institutions in the U.S. as we work to complete additional sales and make this novel technology more broadly available."

"Focal therapy represents today the perfect balance between Active Surveillance and Radical treatments," said Dr. Mehran Movassaghi, M.D., MBA, Assistant Professor of Urology and Director of Men's Health at JWCI. "Focal One is by far the most advanced device to deliver this therapy, and we are proud to be the first in the U.S. to include this in our therapeutic armamentarium for our prostate cancer patients."

About the John Wayne Cancer Institute

Since 1981, the John Wayne name has been committed by the Wayne family to groundbreaking cancer research and education in memory of their father who died of cancer. The John Wayne Cancer Institute at Saint John's Health Center has received worldwide acclaim for advances in melanoma (skin cancer), breast and colon cancer as well as immune therapy of cancer. Other areas of research include prostate and liver cancer. Their unique ability to rapidly turn scientific breakthroughs into innovative approaches to treatment and early detection provides immediate hope to cancer patients from around the globe. For more information on the John Wayne Cancer Institute, please visit www.saintjohnscancer.org.

About EDAP TMS

A recognized leader in the global therapeutic ultrasound market for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for urology 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 2013 as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. For more information on the Company, please visit www.edap-tms.com, and us.hifu-prostate.com.

Forward-Looking Statements

In addition to historical information, this press release may contain forward-looking statements. 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 device. Factors that may cause such a difference also may 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.

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