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EDAP TMS SA : HIFU Pioneer Houston Methodist Hospital Acquires EDAP's Next Generation Focal One HIFU System

March 4, 2019

Houston Methodist's Upgrade from Ablatherm to Focal One Reinforces EDAP's Position as a Leading HIFU Innovator

LYON, France, March 4, 2019 -- EDAP TMS SA (Nasdaq: EDAP)--Houston Methodist Hospital, one of the first hospitals in the U.S. to offer Ablatherm® Robotic High Intensity Focused Ultrasound (HIFU) for patients with localized prostate cancer, has acquired Focal One®, the most advanced HIFU technology available today.

Houston Methodist Hospital initially invested in EDAP's first generation HIFU system, Ablatherm, in early 2016, and within two years of positive experience made the decision to invest in the next generation Focal One device. This confirms the benefits of EDAP's innovative HIFU technology not only for patients, but also in terms of hospital financials. Based on a solid business case built upon Ablatherm's usage, the Hospital showed a rapid return on investment, resulting in the acquisition of Focal One.

"Each proposal for cutting edge medical technology must demonstrate how a new procedure will benefit patients, how it differs from competing technologies and how it contributes to the hospital's overall growth," said Michael Garcia, Senior Vice President, Operations at Houston Methodist Hospital. "In deciding whether to invest in Focal One, we applied these same due diligence principles that we used in the previous technology evaluations. Following the successful business case that we experienced with Ablatherm, we believe Focal One's capabilities will meet and exceed our expectations."

"Focal One realizes the promise of focal therapy for prostate cancer that has long been anticipated," said Brian Miles, MD, Professor of Urology at Houston Methodist's Weill Cornell Medical College who championed the effort to acquire Focal One. "Just like the lumpectomy has become a standard option for treating breast cancer, we can now use Focal One to ablate only the diseased portion of the prostate when appropriate, rather than removing the prostate altogether."

"Houston Methodist Hospital's acquisition of Focal One is a clear validation of Focal One's superior technology," commented Marc Oczachowski, Chief Executive Officer of EDAP TMS. "By upgrading from Ablatherm, Houston Methodist is confirming the strong clinical interest and technological benefits of Focal One, the latest generation HIFU device, compared to first generation devices currently available in the U.S. We believe Focal One is well positioned to become the standard of care for the focal treatment of localized prostate cancer worldwide."

About EDAP TMS SA

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 in Europe and in 2018 in the US 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 <http://www.edap-tms.com>, and us.hifu-prostate.com.

About Houston Methodist Hospital

Houston Methodist Hospital is a not-for-profit, faith-based, 907-bed hospital located in the Texas Medical Center. For nearly 100 years, Houston Methodist has been providing highly specialized health care services to the community and the world through its hospital and our six [Centers of Excellence](#). Medical services include advanced cancer care, heart care, neurology and neurosurgery, orthopedics and sports medicine and much more. Houston Methodist is proud to offer the highest quality patient-focused, family centered care in a spiritual environment. In close affiliation with the Texas Conference of the United Methodist Church, Houston Methodist continues its longstanding commitment to improving the community's health and well-being.

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 not currently considered material or us 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.

Company Contact

Blandine Confort

Investor Relations / Legal Affairs

EDAP TMS SA

+33 4 72 15 31 50

bconfort@edap-tms.com

Investor Contact

Jeremy Feffer

LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com



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