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Bringing New Horizons to Therapy

EDAP Announces Record Preliminary Unaudited Fourth Quarter 2020 Revenue of EUR 15.3 Million [\$18.3 million], an Increase of 28% Year-Over-Year

January 20, 2021

- Record HIFU revenue growth of 50% in the fourth quarter 2020 driven by the sale of eight HIFU devices sold during the quarter
- Achieved sequential quarterly revenue growth throughout 2020 notwithstanding challenges posed by the ongoing COVID-19 pandemic
- Company to announce fourth quarter and full year 2020 results in late March 2021 with accompanying conference call

LYON, France, January 20, 2021 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, reports today preliminary unaudited fourth quarter and full-year revenue for the three and twelve months ended December 31, 2020. For the fourth quarter 2020, the Company anticipates record revenue of EUR 15.3 million [\$18.3 million], as compared to EUR 12.0 million [\$13.3 million] for the fourth quarter of 2019, an increase of 28%. For the full-year 2020, unaudited revenue is anticipated to be EUR 41.6 million [\$47.8 million], as compared to EUR 44.9 million [\$50.2 million] for the full-year 2019, a decrease of 7%, driven entirely by COVID-19-related restrictions.

Marc Oczachowski, EDAP's Chairman and Chief Executive Officer, said: "We are very pleased with this very strong and successful fourth quarter during which we generated record revenue that increased 28% over the prior year period. Of note, HIFU revenue increased 50% over the fourth quarter of 2019, which is all the more impressive in light of the impact the pandemic continues to have on healthcare systems around the world. This reflects the continued interest in HIFU technology and confirms that we have successfully adjusted to this new reality by continuing to grow our sales pipeline. We entered 2021 with renewed momentum, and I look forward to an exciting year."

Note: exchange rates used in the conversion of EUR to USD are: Q4 2020=1.194 and full year 2020=1.147.

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>, and us.hifu-prostate.com.

Forward-Looking Statements

In addition to historical information, this press release contains 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, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. 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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