

## EDAP TMS Strengthens Market Position with Landmark HIFI-2 Data Supporting Focal One® Robotic HIFU in Radiorecurrent Prostate Cancer

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**AUSTIN, Texas, April 30, 2026 - EDAP TMS SA** (Nasdaq: EDAP), the global leader in robotic energy-based therapies, today announced the publication of the **HIFI-2 study**, a large, prospective, nationwide trial evaluating salvage high-intensity focused ultrasound (HIFU) using Focal One Robotic HIFU for the treatment of localized prostate cancer recurrence following radiotherapy.

Published in *European Urology Oncology*, the study titled “*Salvage High-intensity Focused Ultrasound for Prostate Cancer Recurrence after Radiotherapy (HIFI-2 Study)*” represents the largest prospective dataset to date in this clinical setting, including 531 patients treated across more than 30 centers. A link to the publication can be found [here](#).

“This large prospective multicenter study demonstrates that salvage HIFU can achieve clinically meaningful oncologic control while maintaining an acceptable safety profile in patients with localized recurrence after radiotherapy,” said Dr. Guillaume Ploussard, MD, first author of the publication. “In a setting where treatment options offering curative intent remain elusive and often come with significant morbidity, these results are particularly meaningful. Combined with the growing body of clinical evidence, this study further supports HIFU’s transition toward becoming a standard of care for appropriately selected patients.”

These results reinforce salvage HIFU as a viable, organ-preserving treatment option in patients with localized recurrence after radiotherapy, a population historically presented with limited to no treatment options beyond palliative care.

#### Key Findings from HIFI-2:

- 71% androgen deprivation therapy-free survival (ADT-FS) at 30 months
- Up to 84% ADT-FS in favorable, well-selected patient subgroups, including patients with lower pre-HIFU PSA levels ( $\leq 4.5$  ng/mL) and intermediate-risk disease characteristics (Gleason 7 or lower)
- Low rates of severe complications, with an acceptable safety profile
- Preserved quality of life, with no significant deterioration at 12 months

“The publication of the HIFI-2 study marks an important milestone for the field of focal therapy and reinforces the clinical value of Focal One Robotic HIFU in addressing unmet needs in a growing spectrum of prostate conditions,” said Ryan Rhodes, Chief Executive Officer of EDAP TMS. “The final results from this prospective multicenter study provide compelling evidence supporting Focal One as a non-invasive, organ-sparing, function-preserving option for patients facing recurrence after radiotherapy. Today, the NCCN guidelines recommend HIFU as a treatment option for patients with recurrence in the prostate. Medicare and many commercial payors provide coverage for the Focal One HIFU procedure in this clinical setting in accordance with their established coverage policies. In this context, the new HIFI-2 Study further strengthens our leadership position in focal therapy and our commitment to expanding patient access globally.”

#### About European Urology Oncology

European Urology Oncology is a sister journal to European Urology and European Urology Focus, and the first official publication of the European Association of Urology fully devoted to the study of genitourinary malignancies.

The journal aims to deliver high quality research while implementing a multi-disciplinary approach to incorporate Urology, Medical Oncology, Radiation Therapy, Imaging, Pathology and Basic Research with the ultimate goal of advancing research in urological oncology.

European Urology Oncology includes original articles, opinion piece editorials and invited reviews covering clinical, basic and translational research and is published six times a year in electronic format. All submitted manuscripts will be peer-reviewed by a panel of experts before being considered for publication. The journal supports Open Access.

#### About EDAP TMS SA

A recognized leader in robotic energy-based therapies, EDAP TMS develops, manufactures, promotes, and distributes worldwide

minimally invasive medical devices for various conditions using ultrasound technology. By combining the latest technologies in imaging, robotics, and precise non-invasive energy delivery, EDAP introduced the Focal One® in Europe and the United States as a leading prostate focal therapy platform controlled by urologists, with the potential to expand to multiple indications beyond prostate cancer. For more information on the Company, please visit <https://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, 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 10-K.

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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