EDAP Presents Positive Results from Non-Inferiority Study Comparing Outcomes of Focal One HIFU Versus Radical Prostatectomy at EAU23

Mar 21, 2023

Results demonstrate salvage treatment free survival rate (STFS) at 30 months of 90.1% in the HIFU-treated arm versus 86.8% in patients who underwent radical prostatectomy (RP)

The HIFU treated arm showed significant benefits across multiple side effect and quality-of-life measures

LYON, France, March 21, 2023 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), a global leader in robotic energy-based therapies, today announced a recent presentation of positive results from a large, multicenter, non-inferiority study comparing Focal One high intensity focused ultrasound (HIFU) versus radical prostatectomy (RP) at the 38th Annual Congress of the European Association of Urology (EAU), which was held March 10-13, in Milan, Italy.

The study, which ran from April 2015 through September 2019, compared Focal One HIFU versus RP as a first line treatment for patients with localized prostate cancer (grade groups <3). A total of 3,328 patients from 42 treatment centers were included: 1,967 were treated with Focal One HIFU and 1,361 underwent radical prostatectomy surgery. Patients were followed for 30 months.

Select data highlights:

- At 30 months, the STFS was higher in the HIFU arm (90.1%) compared with RP arm (86.8%);
- Risk of salvage treatment was greater than 1.2-fold higher after RP (HR: 0.75, 95% CI [0.64-0.96], p=0.02);
- ICS score, a measure of urinary incontinence, was significantly lower after HIFU (0 vs 1, p<0.001);
- IIEF-5, a measure of erectile function, decreased significantly less after HIFU than after RP despite (median Δ = -4 vs -9 p <0.001);
- Post-procedural benefits of HIFU on both erectile function and urinary continence were demonstrated despite patients in the HIFU-treated group being an average of 9.6 years older (median age was 74.7 years for HIFU vs 65.1 years for RP, p>0.0001);
- After HIFU, median PSA nadir was 0.34 ng/ml and positive biopsy rate was 12.5%; after RP, median PSA was 0.01 ng/ml and positive margins (PM) were reported in 26% of RP-treated patients.

Professor Pascal Rischmann of Rangueil University Hospital in Toulouse, France, and lead investigator of the study, commented, "I was very pleased to present, for the first time, the final consolidated results from this major academic study which was sponsored by the French Association of Urology. This is the largest study ever done to prospectively evaluate HIFU against radical prostatectomy. The aim of this post-approval, non-inferiority study was to compare the survival rates without salvage treatment in both arms, as well as to confirm reimbursement of HIFU in France. These results confirm the growing importance of HIFU in the management of localized prostate cancer."

Marc Oczachowski, Chairman and Chief Executive Officer of EDAP TMS, added, "The positive results from this very large study add to the significant and growing body of evidence demonstrating not only the efficacy of HIFU, but also the superior side effect profile which can meaningfully impact patients' quality of life. With a growing recognition of the clinical benefits of HIFU treatment, EDAP continues to expand global access to Focal One HIFU so that more prostate cancer patients have the opportunity to realize the treatment benefits of our therapeutic HIFU technology."

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. 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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