EDAP TMS SA : EDAP Announces CIGNA as First Major U.S. Private Health Insurer to Cover HIFU for Prostate Procedure

March 21, 2018

Insurer Takes its Cue from Updated NCCN Guidelines,
Which Recognizes HIFU as Salvage Treatment for Prostate Cancer

Lyon, France, Austin, TX -- March 21, 2018 - EDAP TMS SA (Nasdaq: EDAP) today announced that CIGNA became the first major U.S. private health insurance company to reimburse prostate cancer patients who failed radiation and are eligible for High-Intensity Focused Ultrasound (HIFU) as a salvage therapy. EDAP TMS manufactures the Ablatherm® Robotic High Intensity Focused Ultrasound (HIFU) device, used by urologists in the U.S. for prostate tissue ablation.

The CIGNA move signals a shift in the private health insurance market regarding HIFU procedures. CIGNA is one of the five largest payors in the U.S., covering 15.9 million lives. HIFU as a salvage therapy is already reimbursed by a number of regional payors, including Asuris Northwest Health in Washington State and Priority Health in Michigan.

The CIGNA policy aligns with National Comprehensive Cancer Network (NCCN) guidelines recognizing that some men with localized prostate cancer may benefit from salvage HIFU.
The policy acknowledges HIFU as "medically necessary as a local treatment for recurrent prostate cancer following radiation therapy" for patients meeting specific medical criteria.

HIFU works by directing high-frequency sound waves that heat up and burn off the targeted area of the prostate. In 2015, the FDA cleared HIFU for prostate tissue ablation. Because no radiation is involved HIFU is considered a "repeatable technology," which means that unlike conventional radiotherapy or surgical treatments patients can repeat the HIFU procedure if necessary.

Typically performed in an outpatient setting, HIFU therapy is non-invasive, and according to the CIGNA policy it "remains unique compared with other modalities for localized prostate cancer in that it has been proposed to result in much less adjacent tissue damage."

The CIGNA policy covers HIFU as a salvage therapy for patients whose early stage prostate cancer has not metastasized and who meet both of these criteria:

- positive, recent (i.e., repeat) transrectal ultrasound guided (TRUS) biopsy completed due to suspicion of local recurrence of prostate cancer
- candidate for local therapy alone as evidenced by ALL of the following:
    - original clinical stage T1-T2, NX or N0
    - recent PSA (Prostate Specific Antigen) of less than 10ng/mL
    - absence of distant metastases

Often, patients experiencing a recurrence of prostate cancer who are no longer candidates for radiation therapy, are limited to active surveillance, or "watchful waiting," to assess progress of the disease. HIFU offers a medical alternative to this approach for some of these patients.

In its review of the medical literature, the CIGNA policy cites a Hayes Directory Report that validates the safety and efficacy of HIFU for patients with localized prostate cancer that recurred after they received primary treatment via radical prostatectomy (RP) or External Beam Radiation Therapy (EBRT).

That report goes on to state that "the best available studies of ultrasound-guided HIFU for localized recurrent prostate cancer without metastatic disease at the time of treatment have consistently found that most patients had a reduction in PSA level, acceptable local tumor control, remained free of disease progression and survived for five years or longer after treatment."

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® (currently pending FDA clearance) 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.

Contact:
Shelly Gordon
sgordon@g2comm.com
(480) 685-3252

Investor Contact
Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com

Source: EDAP TMS S.A.