



FDA approves the 1st trial with Theraclion's vein therapy in the US

Malakoff, September 21st, 2021 - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE, PEA-PME eligible), an innovative company specialized in echotherapy treatment (using High Intensity Focused Ultrasound or HIFU), announces FDA (Food & Drug Administration) approval for the first trial with SONOVEIN in the United States (US). After this clinical trial, a full pivotal study will be conducted for FDA review for market authorisation.

The study will be initiated as soon as possible and conducted in a well-known New Jersey Center by Steve Elias MD FACS DABVLM, an internationally recognized vein specialist with more than 30 years experience in the treatment of venous disease. The study will be conducted in collaboration with Dr Nicos Labropoulos and Dr Antonios Gasparis both internationally recognized vein specialists with more than 30 years experienced too.. “We are excited to be the first in the US to assess this breakthrough technology which takes superficial vein treatment to the next level: completely non-invasive and transcutaneous. It will be great for patients” said Dr Steve Elias, MD FACS DABVLM.

“We are proud that SONOVEIN, our technology, was chosen to be assessed by renowned experts in vein treatments. We are hoping to have soon the first US patients treated with our extra corporeal system for their varicose veins. Our qualitative pre-clinical studies, the CE marking since 2019 and our clinical data from our European centers should support a fast approval for our pivotal study” said Michel Nuta, MD, Chief Medical Officer, Vice-President Veins Theraclion SA.

It is a crucial milestone for Theraclion to access the largest market for varicose veins with an estimated 2,3 million procedures representing healthcare spending of \$ 5 Billion. It has historically been under penetrated but will expand with the development of painless and non-invasive technologies such as SONOVEIN.

SONOVEIN is the only non-invasive option, without scars and without incisions. The advanced technological solution allows optimal treatment procedure in a reduced duration and improves patient experience.

About Theraclion

Theraclion has developed an innovative echotherapy solution using High Intensity Focused Ultrasound for the treatment of varicose veins, SONOVEIN®. The treatment solution, which obtained CE marking in April 2019, is based on the leading-edge echotherapy treatment expertise developed by Theraclion over years for non-invasive ablation of breast fibroadenomas and thyroid nodules using its ECHOPULSE® solution. Further improvements to the ECHOPULSE technology are the foundation for SONOVEIN to provide the only non-invasive ablation therapy for varicose veins. This procedure allows for treatment without a catheter, chemical injection, or incision. An operating room is not necessary, and the treatment can be performed at a doctor's offices or in clinics, as well as in hospitals. Venous pathology is widespread worldwide and generates around 5 million treatment procedures per year, according to Millennium research Varicose Vein Device Market Study 2015. Theraclion's technological solutions are based on high-tech ultrasound medical devices that are precise and easy to use for practitioners.

Located in Malakoff, near Paris, Theraclion brings together a team of 25 people, more than half of whom are dedicated to R&D and clinical trials.



For more information, please visit the Theraclion website: www.theraclion.com and the patient site: <https://echotherapie.com/echotherapy/>

Theraclion is listed on Euronext Growth Paris
Eligible for the PEA-PME scheme
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