



SONOVEIN® FDA PIVOTAL STUDY TREATMENTS COMPLETED: THERACLION REACHES KEY MILESTONE ON SCHEDULE

Malakoff, June 24, 2024, 6:30 pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE innovative company developing a robotic platform for non-invasive high-intensity focused ultrasound (HIFU) therapy, announces today that treatments in the United States' FDA (Food & Drug Administration) pivotal study for SONOVEIN® have concluded, in accordance with the scheduled timeline.

A key milestone in the FDA approval process for SONOVEIN®

A total of 70 patients have been treated with Sonovein in the clinical trial. Four leading centers took part in this study, in the U.S. and in Europe.

Principal investigator Steve Elias MD commented, *"I have been involved with many emerging technologies and initial clinical trials. It is very satisfying to have completed the VEINRESET trial treatments using Sonovein. Sonovein is the only extracorporeal, transcutaneous technology capable of treating superficial venous insufficiency. The patient experience and initial results of this trial are extremely promising. I look forward to the final results of the multi-center clinical trial. This has great potential to be an advancement in the management of superficial venous disease."*

Theraclion's Chief Medical Officer Michel Nuta MD added, *"We are happy to have completed the always important recruitment phase and to have reached the FDA target for treatment numbers. We will now focus on the study follow-up phase and continue accumulating valuable clinical experience in our top-notch centers."*

Results to be released after 12-month follow-up

Following the successful completion of a feasibility study in 2022, the FDA pivotal study was initiated on schedule at the end of 2023. With the conclusion of the treatment phase, a 12-month follow-up period is now beginning, and the study results will be available in the summer of 2025. The market approval application will be submitted to the FDA as soon as the study report becomes available in the second half of 2025, and an approval is expected early 2026 but will depend on the regulatory agency review time.

Martin Deterre, CEO of Theraclion, concludes: *"We are very satisfied to have reached another key milestone on schedule. We look forward to seeing and presenting the results of this strategic study after the follow-up period next year."*



About Theraclion

Theraclion is a French MedTech company committed to developing a non-invasive alternative to surgery through the innovative use of focused ultrasound.

High Intensity Focused Ultrasound (HIFU) does not require incisions nor an operating room, leaves no scars, and allows patients an immediate return to their daily activities. The HIFU treatment method concentrates therapeutic ultrasounds to an internal focal point from outside of the body.

Theraclion develops the HIFU, CE-marked, platform for varicose veins treatment SONOVEIN®, having the potential to replace millions of surgical procedures every year. In the United States, SONOVEIN® is an investigational device that is limited to investigational use; it is not available for sale in the US.

Based in Malakoff (Paris), the Theraclion team is made up of about 30 people, mainly in technological and clinical development.

For more information, please visit www.theraclion.com and follow the account on [LinkedIn](#).

Theraclion is listed on Euronext Growth Paris

Eligible for the PEA-PME scheme

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