THERACLION ANNOUNCES SUCCESSFUL U.S. FDA PIVOTAL STUDY WITH 96.8% OCCLUSION RATE

Malakoff, September 15, 2025, 6:30 pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing Sonovein®, the first platform for non-invasive High-Intensity Focused Ultrasound (HIFU) varicose vein treatment, announced top-line results from its VEINRESET pivotal U.S. clinical trial today.

- **Primary endpoint met**: Occlusion rate at 12 months was 96.8%, confirming strong efficacy.
- **Excellent safety profile**: No serious or unanticipated adverse events, only one mild adverse event reported throughout the study.
- **Solid secondary endpoints**: Reflux abolition rate of 98.5%.
- **70 patients across four centers** were enrolled and treated in New York (U.S.), New Jersey (U.S.), Vienna (Austria), and Prague (Czech Republic).

"*These results demonstrate that completely non-invasive HIFU with Sonovein® is equal to state of art methods available now. It is certainly a reliable and viable option equivalent to our traditional treatments with other patient benefits,*" said Steve Elias, MD, Principal Investigator.

"*Reaching such a high occlusion rate with a very favorable safety profile provides robust evidence for the clinical value of Sonovein® in treating venous disease. These clinical results support our strategy for FDA submission and potential entry into the U.S. market. We aim to provide U.S. varicose vein patients with the advantages of our non-invasive, disruptive Sonovein® technology, which has already been used in over 3,500 procedures and commercially adopted by more than a dozen centers in Europe and the Middle East,"* said Martin Deterre, CEO of Theraclion.

The VEINRESET study was a single-arm, prospective, multi-center clinical trial to assess the safety and efficacy of Theraclion's Sonovein® device in treating primary insufficiency of Great Saphenous Vein (GSV). The study results showed that 96.8% of treated patients achieved complete vein closure at 12 months, with a 95% confidence interval of 88.3% to 99.2%, thereby meeting the primary endpoint. All secondary endpoints demonstrated favorable device efficacy and safety. At 12-month follow-up, 98.5% of patients did not have reflux. Pain disappeared in all patients, and symptoms were completely resolved in most patients, according to the Venous Clinical Severity Score (rVCSS). None of the patients underwent complementary procedures. Both patients and investigators were satisfied with the device/procedure outcome.

Taken together, the study successfully demonstrated that using HIFU generated by Sonovein® is safe and effective for the treatment of symptomatic primary GSV insufficiency.

Next steps

These results will form the basis of Theraclion's planned submission to the U.S. Food and Drug Administration (FDA). Authorization from FDA would enable Theraclion to access the U.S. market, the largest vein treatment market worldwide.

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 or an operating room. HIFU treatment concentrates therapeutic ultrasounds on an internal focal point from outside the body.

Theraclion is developing Sonovein®, a CE-marked, HIFU platform for varicose vein treatment, that could replace millions of surgical procedures every year. To date, Sonovein® has been adopted by more than a dozen centers worldwide and used in over 3,500 procedures. In the U.S., Sonovein® is currently limited to investigational use and is not available for sale.

For more information, please visit www.theraclion.com and follow the LinkedIn account.

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