THERACLION ANNOUNCES SONOVEIN FDA SUBMISSION FOLLOWING A STRONG YEAR OF REGULATORY AND CLINICAL ACHIEVEMENTS

Malakoff, December 9, 2025, 6:30 pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing Sonovein®, a robotic platform for non-invasive High-Intensity Focused Ultrasound (HIFU) varicose vein treatment, reports today the key regulatory and clinical communication achievements of the past year across congresses, publications, and expert presentations.

Regulatory update: FDA submission

Theraclion announces that the full dataset from the U.S. Food and Drug Administration pivotal study has been submitted to the FDA on schedule as part of the De Novo clearance process for Sonovein®. Based on typical FDA review timelines for comparable devices, a decision is anticipated around mid-2026. FDA clearance would authorize U.S. commercialization, giving access to the largest varicose vein treatment market.

Additional regulatory progress in Europe and China

In 2025, Sonovein® also achieved key regulatory milestones, including EU MDR certification and compliance with China's GB 9706.1-2020 standard, strengthening its pathway to long-term commercialization in Europe and future market access in China.

New publications and scientific evidence

In 2025, several peer-reviewed publications further strengthened the clinical evidence supporting Sonovein® and its non-invasive HIFU technology, including:

- Rodríguez Carvajal *et al*., in *Phlebology,* found 94% to 97% efficacy on 164 veins at 12 months
- Izquierdo Lamoca *et al*., in *Journal of Vascular Surgery: Venous and Lymphatic Disorders,* demonstrated 95% efficacy on 204 legs at 24 months
- Casoni *et al.,* in *Phlebology,* reported 100% efficacy at 12 months on 25 perforator veins

These results were complemented by Theraclion's FDA pivotal study, which confirmed strong durable efficacy with 96.8% occlusion rate at 12 months, and an excellent safety profile across four international centers.

A year marked by strong congress presence

In 2025, Sonovein® was featured in 16 international congresses, strengthening its visibility among vascular surgeons, phlebologists and vein-care specialists worldwide. This included 2 major

congresses in the U.S.—the *Venous Symposium* and *VEITHsymposium* in New York., 4 events in France, and 8 congresses across the rest of Europe.

The Theraclion Sales & Marketing team was present with a booth at 7 of the 15 major conferences, ensuring direct engagement with physicians, hospital administrators, and potential new centers. The Sonovein's disruptive value proposition combined with demonstrated efficacy was very well received by the market.

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 MDR CE-marked, robotic 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 not available for sale.

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

Theraclion is listed on Euronext Growth Paris
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