THERACLION OBTAINS FDA AUTHORIZATION FOR SONOVEIN®, OPENING A NEW ERA IN NON-INVASIVE VEIN CARE IN THE UNITED STATES

- Sonovein® becomes the first non-invasive HIFU platform to receive U.S. marketing authorization for the treatment of superficial venous reflux in Great Saphenous Vein (GSV) segments through the FDA's De Novo pathway.
- Access to the world's largest varicose vein treatment market opens a transformative growth opportunity for Theraclion.
- Following years of technological development and clinical validation, Theraclion enters a new phase focused on commercial deployment and adoption.
- With months of preparation completed and its U.S. subsidiary established, Theraclion is ready to execute the commercial launch in the U.S.

Malakoff, November 5, 2026, 6:00 pm CET - THERACLION (ISIN: FR0010120402; Ticker: ALTHE), an innovative company developing Sonovein®, a platform for the non-invasive treatment of varicose veins using High-Intensity Focused Ultrasound (HIFU), today announces that the U.S. Food and Drug Administration (FDA) granted De Novo marketing authorization for Sonovein® on November 4, 2026. In the United States, Sonovein® is intended for the coagulation of blood vessels in patients with superficial vein reflux in the Great Saphenous Vein (GSV) segments. Superficial venous reflux, most often involving the GSV, is the main cause of varicose veins, a condition affecting approximately one third of adults.

This decision marks a major advance for U.S. patients, bringing access to a novel technology that treats targeted veins entirely from outside the body, without an incision or an intravascular catheter.

For Theraclion, the authorization represents a historic turning point. It brings years of research, technological development and clinical validation to fruition, while opening the U.S. market and a new phase of commercial growth.

A historic milestone and a new chapter

"*This authorization marks the culmination of years of clinical and regulatory work and opens a defining new chapter for Theraclion. Sonovein® enables entirely non-invasive vein treatment, without incisions or catheters. We are proud to bring this fundamental advance to U.S. patients and physicians. I thank our teams, clinical investigators, partners and shareholders, whose dedication and belief in our vision helped make this achievement possible. We also thank the FDA for its constructive engagement throughout the review process*," said Martin Deterre, Chief Executive Officer of Theraclion.

"*This milestone also marks the starting point for U.S. commercialization. Our priority is to establish successful treatment centers, build sustained adoption and deliver growth. After months of preparation, with our launch plan refined and our U.S. subsidiary, Sonovein Inc., established, we are ready to hit the ground running.*"

Clinical evidence supporting a new device classification

The FDA's De Novo pathway is intended for novel devices of low to moderate risk for which no legally marketed predicate device exists. This decision establishes a new device classification. Sonovein® becomes the first and only FDA-authorized HIFU platform offering a non-invasive treatment option for patients with varicose veins.

Authorization is supported by the VEINRESET pivotal study, involving 70 patients across four U.S. and European centers (ClinicalTrials.gov identifier: NCT05926830). The study met its primary endpoint with a 96.8% GSV occlusion rate at 12 months, supporting durable vein closure through non-invasive treatment. No serious or unanticipated adverse events were reported, and only one mild adverse event was observed.

Ready to execute the U.S. launch

Theraclion has spent months preparing its U.S. market entry, advancing the administrative, corporate and operational groundwork ahead of FDA authorization. Its U.S. subsidiary, Sonovein Inc., has been incorporated, and key launch preparations are already in place, enabling the team to move directly into commercial execution.

A dedicated Category III CPT code has been active since October 1, 2026, enabling standardized reporting and tracking of non-invasive HIFU vein procedures in the U.S. This code marks an initial step towards developing coverage and payment pathways, pillars of the Company's commercial deployment plan.

The initial rollout will establish reference treatment centers through physician training, clinical onboarding and technical and service support. Successful implementation and sustained utilization will provide the foundation for wider U.S. adoption.

An opportunity to transform Theraclion's scale

FDA authorization opens the world's largest varicose vein treatment market, removing a major regulatory barrier and strengthening Theraclion's engagement with physicians, treatment networks and potential commercial partners. A growing installed base and treatment volumes could substantially expand the business and its recurring revenue, supported by disciplined execution.

The U.S. launch complements commercial expansion in Europe, market-access development in China, and distributor-led growth elsewhere, starting with the Middle East following the recent Saudi Arabian authorization.

Theraclion's ambition is to establish Sonovein® as a leading platform in non-invasive vein care and translate its technological and clinical achievements into lasting commercial value.

About Theraclion

Theraclion is a French MedTech company committed to developing non-invasive alternatives to surgery through the innovative use of focused ultrasound. High-intensity focused ultrasound (HIFU) concentrates therapeutic ultrasound toward an internal focal point from outside the body.

Theraclion's Sonovein® platform applies this principle to varicose vein treatment, delivering energy to the targeted vein through the skin, without an incision or an intravascular catheter.

Sonovein® is CE-marked under the MDR (EU 2017/745) and has received De Novo marketing authorization in the U.S. from the FDA, making it the first and only HIFU platform authorized in Europe and the United States to offer a non-invasive treatment option for patients with varicose veins.

Designed, developed and manufactured in France, Sonovein® has been adopted by more than twenty centers worldwide and has been used in more than 4,000 procedures.

Based in Malakoff (Paris), the Theraclion team consists of approximately 40 people.

For more information, please visit **www.theraclion.com** and follow us on **LinkedIn**.

Disclaimer

This press release contains information about Theraclion's objectives and forward-looking statements. This information is not historical data and should not be interpreted as a guarantee that the facts and data stated will occur. This information is based on data, assumptions and estimates considered reasonable by Theraclion. Theraclion is not in a position to anticipate all the risks, uncertainties or other factors likely to affect its business, their potential impact on its business or the extent to which the materialization of a risk or combination of risks could have results materially different from those mentioned in any forward-looking information. This information is given only as of the date of this press release. Theraclion undertakes no obligation to publicly update this information or the assumptions on which it is based, except as may be required by law or regulation.

This press release may be drafted in the French and English languages. If both versions are interpreted differently, the French language version shall prevail.

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