



## FDA APPROVAL FOR PIVOTAL VARICOSE VEINS STUDY WITH THERACLION'S SONOVEIN®

**Malakoff, April 17<sup>th</sup>, 2023, at 06:30pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing a scalable robotic platform for non-invasive ultrasound therapy,** announces today that the US Food&Drug Administration (FDA) has approved its Investigational Device Exemption (IDE) application to initiate the multi-center pivotal study VEINRESET for the treatment of primary insufficiency of great saphenous veins with SONOVEIN®.

### **Theraclion's most significant clinical trial to date**

“We are pleased to announce this major milestone”, stated Michel Nuta, MD, Chief Medical Officer and Vice President Veins at Theraclion, “and want to formally thank our physician advisors and our regulatory team for their leadership and contributions to this landmark study.”

“We believe that this key study will confirm the positive findings of the FDA feasibility study, completed just two months ago, and will ultimately allow us to commercially address the US market”, stated Yann Duchesne, Executive Chairman of Theraclion.

The pivotal study will be conducted in four scientifically prominent centers in the United States and in Europe. Principal US investigator, Steven Elias, MD, is the director of the Center for Vein Disease at Englewood Hospital, New Jersey, and a Fellow of the American Board of Venous and Lymphatic Medicine and of the American College of Surgeons. Patients treatments are planned to start later this year.

### **Paving the way to the biggest varicose vein market in the world and beyond**

The technology has been endorsed by major key opinion leaders in both the US and Europe and its results have been presented in numerous scientific congresses.

This clinical trial approval is a key development in Theraclion's commercial strategy, as the North American market represents more than 45% of the global market, driven by the US. Compared to Europe, the US is a higher price market and allows for more homogenous market access strategy, and therefore a faster market penetration. In addition, accessing the US market is a major milestone and driver for global sales uptake.

Addressable annual varicose veins procedures globally are expected to rise up to 4.3M in 2033 representing a potential \$2.1B medical device market for Theraclion.



## **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, leaves no scars, and allows patients an immediate return to their daily activities. Echotherapy, as the HIFU treatment method is called, concentrates therapeutic ultrasounds to an internal focal point from outside of the body.

Theraclion has developed two CE-marked robotic platforms delivering echotherapy: SONOVEIN® for varicose veins and ECHOPULSE® for breast fibroadenoma and thyroid nodules. Each represents the potential to replace millions of surgical procedures every year.

Based in Malakoff (Paris), Theraclion's team of 30 people is mostly made up of engineers and researchers. Designing and manufacturing the products, they also support a limited number of reference centers, where treatment protocols are defined, paving the way for the clinical trial required to obtain US market access.

**For more information, please visit [www.theraclion.com](http://www.theraclion.com) or [www.echotherapy.com](http://www.echotherapy.com) and follow the account on [LinkedIn](#).**

Theraclion is listed on Euronext Growth Paris

Eligible for the PEA-PME scheme

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