



THERACLION ACHIEVES AN IMPORTANT MILESTONE ON THE ROAD TO THE U.S. MARKET: FIRST PATIENTS TREATED WITH SONOVEIN® AS PART OF THE FDA-APPROVED PIVOTAL STUDY

Malakoff, October 24, 2023, 06:30pm - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE), an innovative company developing a scalable robotic platform for non-invasive ultrasound therapy, announced today that it has launched the first treatments for its FDA-approved pivotal study on the treatment of varicose veins using SONOVEIN® in the United States.

Theraclion's strategy is to gain access to key markets in the United States and China as early as possible. The first patient treatments are an essential step towards accessing the world's leading varicose vein market.

The Food & Drug Administration (FDA) approved this clinical trial a few months ago, following a successful initial feasibility study last year. Renowned doctor Steve Elias, Director of the Center for Vein Disease at a prestigious New Jersey hospital and member of the renowned American Board of Venous and Lymphatic Medicine and American College of Surgeons, is the principal investigator of this trial, which will be conducted at four centers of excellence in the U.S. and Europe. Results will be available after a 12 month follow-up period, in accordance with the FDA-approved protocol.

Martin Deterre, Chief Executive Officer, commented "*These first patients treated in the pivotal study demonstrate the progress made by the Theraclion team, in a timeline perfectly aligned with our defined strategic roadmap. Enrollment is expected to take several months, with the ultimate goal of U.S. market approval by early 2026.*"

Michel Nuta, MD, Chief Medical Officer, Vice President Veins, added "*The study aims to enable access to this unique extracorporeal technology, without catheters or artificial chemicals, for U.S. patients in the near future.*"

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. 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 representing the potential to replace millions of surgical procedures every year.

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

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

Theraclion is listed on Euronext Growth Paris
Eligible for the PEA-PME scheme
Mnemonic: ALTHE - ISIN code: FR0010120402
LEI: 9695007X7HA7A1GCYD29

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