THERACLION STRENGTHENS ITS GROWTH PROSPECTS IN THE MIDDLE EAST BY OBTAINING MARKETING AUTHORISATION FOR SONOVEIN® IN SAUDI ARABIA

Malakoff, 3 November 2026, at 6:00 pm CET – THERACLION (ISIN: FR0010120402; Ticker: ALTHE), an innovative company developing Sonovein®, a robotic platform for the non-invasive treatment of varicose veins using high-intensity focused ultrasound (HIFU), announces that it has obtained the Medical Device Marketing Authorization for Sonovein® from the regulatory authority of Saudi Arabia, the *Saudi Food and Drug Authority* (SFDA). It allows Theraclion to market the Sonovein® therapeutic ultrasound platform in the country.

The authorisation, granted on 28 October 2026 under Saudi medical device regulations, opens access to one of the leading healthcare markets in the Middle East, at a time when the Kingdom is investing significantly in modernising its healthcare system.

An authorisation that supports Theraclion's international commercial strategy

Theraclion is pursuing a commercial strategy tailored to its key markets: preparing its entry into the United States, subject to FDA authorisation; continuing the roll-out of Sonovein® in Europe; developing its access to the Chinese market with its partner Furui and their local joint venture; and expanding its presence in the rest of the world through local distributors.

On this last front, the Middle East is a development priority. Theraclion already has several Sonovein® systems installed in the region and intends to build on this emerging presence to strengthen its commercial momentum there. The authorisation obtained in Saudi Arabia enables the Company to extend its commercial development with local distributors to the Saudi market and to support the expansion of the network of Sonovein® user centres in the Middle East.

"This authorisation represents a tangible step forward in Theraclion's commercial development in the Middle East and is further recognition of the quality of our technology. Saudi Arabia is a dynamic healthcare market, committed to adopting innovative medical technologies, and we look forward to making Sonovein® available to physicians and patients in the Kingdom. This milestone will also support our regional development, which relies on local distributors. Our objective is to translate this opening into new installations and growing use of Sonovein®, as part of our international commercial strategy", said Martin Deterre, Chief Executive Officer of 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) requires no incision or operating theatre, leaves no scar and allows patients to resume their daily activities immediately. The HIFU method focuses therapeutic ultrasound on an internal focal point from outside the body.
Theraclion is developing Sonovein®, a robotic HIFU platform for the treatment of varicose veins, CE-marked under the MDR (EU 2017/745), with the potential to replace millions of surgical procedures every year. To date, Sonovein® has been adopted by more than twenty centres worldwide and has been used in more than 4,000 procedures. In the United States, Sonovein® is not yet available for sale.

Based in Malakoff (Paris), the Theraclion team comprises around forty people.

For more information, please visit www.theraclion.com and follow our LinkedIn page.

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

Theraclion contact

Martin Deterre
Chief Executive Officer
contact@theraclion.com