The FDA accepts to review Theraclion's submission for approval of an Echopulse pivotal trial in the US

Malakoff – June 3, 2015 – THERACLION (Alternext, FR0010120402 - ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced that it has filed a Pre-Submission for discussion with the Food and Drug Administration (FDA) regarding the regulatory pathway and clinical data requirements for the Echopulse System. Theraclion intends to conduct a prospective, randomized, multi-center pivotal study of the Echopulse to further evaluate the device for ablation of breast fibroadenoma. The study will evaluate changes in fibroadenoma volume and symptoms as well as patient satisfaction.

The proposed pivotal study follows two prior investigations, including a European multi-center study in 42 women with 51 breast fibroadenomas. This study, as reported earlier this year by Pr. Kovatcheva *et al.* in the *Journal of Therapeutic Ultrasound,* demonstrated an average decrease in fibroadenoma volume of 72.5% at the 12-month follow-up, with minimal pain and adverse events related to the treatment.

A pilot study is also ongoing at the University of Virginia, Charlottesville, USA, to further evaluate the Echopulse for treatment of breast fibroadenomas. The data from both studies, together with the proposed pivotal study, will support the company's premarket submission. The company anticipates a meeting with the FDA in the third quarter of 2015 to discuss the final design of the clinical study.

"*This represents a new milestone for Theraclion*," says David Caumartin, CEO of Theraclion. "*The US market for palpable fibroadenoma is around 600,000 per year. Most women are currently offered open surgical excisions. In an indication where pain management and physical and psychological discomfort are the main factors to consider, a non-invasive treatment solution like the one offered by Echopulse provides women with a breakthrough alternative. Many patients prefer a treatment that does not require an incision and most are expected to undergo the procedure under local anesthetic with no hospitalization. This echotherapy alternative offers benefits for both the patient and the healthcare system*."

The Echopulse is an experimental device in the United States and is limited to investigational use. It is not available for sale.

About Theraclion
Based in Malakoff, near Paris, Theraclion is a French company specialized in leading-edge medical devices for echotherapy. Theraclion designs, develops and markets a medical device (Echopulse®) that combines advanced ultrasound imaging and HIFU therapy. Theraclion is ISO 13485 certified and has received the CE mark for non-invasive ablation of breast fibroadenomas and thyroid nodules. A full 52% of its 25-strong team are dedicated to R&D and clinical trials. For more information, visit http://www.theraclion.com.

Theraclion is listed on Alternext Paris
Mnemonic: ALTHE - ISIN Code: FR0010120402

Contacts :

Theraclion
David Caumartin
Directeur Général
Tél. : +33 (0)1 55 48 90 70
david.caumartin@theraclion.com

NewCap
Communication Financière et Relations Investisseurs
Emmanuel Huynh / Valentine Brouchot
Tél. : +33 (0)1 44 71 94 94
theraclion@newcap.fr

ALIZE RP
Relations Presse
Caroline Carmagnol / Valentine Boivin
Tél. : + 33 (0)1 44 54 36 63
theraclion@alizerp.com