Theraclion makes substantial progress towards market access for Echopulse® in the US

- **Pivotal trial for Breast Fibroadenoma at over 25% treatment completion: UVA & NYU represent the two largest recruitment centers**

- **UVA has treated its first metastatic breast cancer patient with a combination of echotherapy and pembrolizumab**

- **Studies demonstrate potential for echotherapy to provide a non-invasive option in several new indications**

Malakoff, France – October 26, 2017 – THERACLION (Euronext Growth, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced that Echopulse echotherapy has achieved milestones reflecting its progression towards US market access. The number of patients treated into the Echopulse FDA pivotal trial for breast fibroadenoma has progressed rapidly and the first metastatic breast cancer patient has been treated with Echopulse in combination with immunotherapy. Theraclion also exposed the potential for echotherapy to provide a non-invasive option for multiple indications from benign to malignant tumors, as well as for vein pathologies.

Over 25% of pivotal trial breast fibroadenoma patients have been treated

The U.S. pivotal clinical trial to evaluate the safety and efficacy of Echopulse® echotherapy as a non-invasive treatment of breast fibroadenomas (BFAs) has already treated more than 25% of patients.

The prospective clinical trial will enroll approximately 100 patients at four centers in the U.S. and two centers in Europe. The centers include University of Virginia School of Medicine (UVA), NYU Langone Bellevue, Montefiore Medical Center (NY), New York-Presbyterian/Columbia University Medical Center, Tübingen University Hospital, Germany and the University Hospital of Endocrinology of Sofia, Bulgaria. Two-thirds of the patients treated to date were treated by UVA, led by Dr. David Brenin, MD, chief of breast surgery, and at NYU, led by Dr. Kathie-Ann Joseph, MD, Chief of the Breast Surgery Service.

Michel Nuta, MD, Chief Medical Officer of Theraclion, commented: *"UVA and NYU, two centers of excellence in their fields, have combined their expertise in the field of focused ultrasound (HIFU) and their efforts in providing access to health care for sometimes underserved populations. This has led to a fruitful collaboration extending to all US sites involved in the study."*

First Metastatic Breast Cancer treated at UVA with the combination of echotherapy and immunotherapy

Theraclion is also announcing the treatment of the first patient in a clinical trial evaluating the combination of Echopulse Echotherapy and immune-therapy with pembrolizumab in women with metastatic breast cancer. The rationale of the study is based on the published observations that HIFU treatment induces an immune response. The hypothesis is that this response could enhance treatment with a checkpoint inhibitor. The study will enroll 12 patients with a primary objective to assess the adverse event profile of pembrolizumab and focused ultrasound therapy in patients with metastatic

breast cancer and to determine whether the addition of pembrolizumab to focused ultrasound increases the proportion of CD8+ tumor infiltrating lymphocytes (ratio CD8+/CD4+) in the primary ablation zone. Further details are posted on www.clinicaltrials.gov (identifier NCT03044054).

Sylvain Yon, PhD, Deputy CEO of Theraclion, said: "*Echopulse® is particularly suited to this combined treatment as it is the only completely noninvasive system with an articulated arm providing flexible access to the target. We are looking forward to the results of this study designed to extend the clinical results in benign tumors to cancerous diseases. This is a critical step for breast specialist users, gynecologists, oncologists and radiologists who are eager to explore this new strategy to fight cancer."*

Echotherapy to provide a non-invasive option for multiple indications

In addition, the company initiated a clinical trial two months ago to investigate the use of Echopulse® to treat insufficient superficial and perforating veins of the lower limb (varicose veins) with non-invasive High Intensity Focused Ultrasound (HIFU). The single-site trial, based in Austria, has already enrolled more than 25% of the cases planned for the study. Further details are posted on www.clinicaltrials.gov (identifier NCT03304834).

Echopulse is already CE-Marked for both breast fibroadenomas and thyroid nodules where it has proven its efficacy and tolerability. As of October 2017, the number of publications increased significantly with 9 new articles (1 on the breast and 8 on the thyroid) in renowned journals such as *Radiology* or *Thyroid*, bringing the total number of publications to 18. It should be noted that the first promising results in Graves' disease, another new indication for echotherapy, were published in the prestigious journal *Radiology*. Latest results from the FDA-feasibility trial evaluating echotherapy in BFA treatment will be presented during RSNA 2017 in Chicago, one of the most prestigious conferences in the US.

"Although our focus since founding the company has been on the non-invasive treatment of thyroid nodules and BFAs, we also know that the technology has potential in a wide variety of conditions, which are currently treated with invasive approaches or have few good options," said Michel Nuta M.D., CMO of Theraclion. *"Having shown the efficacy of Echopulse for the treatment of BFA and thyroid nodules in Europe and progressing on doing the same for BFA in the U.S., we are now actively exploring these two additional indications with the ultimate objective of offering new and better treatment options to patients and their physicians. We look forward to reporting on the results of these two studies."*

About the "Veins" Clinical Trial of the Echopulse® device

The subjects in this trial are patients who have been diagnosed with CVD and are presenting with venous reflux associated with lower limb superficial venous network insufficiency, recurrence at the thigh/groin level or perforator incompetence.

This is designed as a single center, prospective, single arm, open-label trial involving 35 subjects. The trial includes a single HIFU treatment session and 3 months of follow-up.

Subjects will undergo Duplex ultrasound examinations before and at each post procedural follow-up visit.

About Theraclion

Theraclion is a French company specializing in high-tech medical equipment using therapeutic ultrasound. Drawing on leading-edge technologies, Theraclion has designed and manufactured an innovative solution for echotherapy, the Echopulse®, allowing non-invasive tumor treatment through ultrasound-guided high-intensity focused ultrasound. Theraclion is ISO 13485 certified and has received the CE mark for non-invasive ablation of breast fibroadenomas and thyroid nodules. Based in Malakoff, near Paris, France Theraclion has brought together a team of 35 people, 50% of whom are dedicated to R&D and clinical trials. For more information, please visit Theraclion's website: www.theraclion.com

Theraclion is listed on Euronext Growth Paris
PEA-PME eligible
Mnemonic: ALTHE - ISIN Code: FR0010120402

Contact:

Theraclion
David Caumartin
Chief Executive Officer
Tel.: +33 (0)1 55 48 90 70
david.caumartin@theraclion.com

Kalima
Press Relations
Sarah Hachemi
Tel.: + 33 (0)1 42 21 56 36
shachemi@kalima-rp.fr