THERACLION'S Echopulse® new clinical data to be presented during RSNA by the University of Virginia

- University of Virginia will present at Radiological Society of North America (RSNA) its latest U.S. clinical data for breast fibroadenomas
- Echotherapy is a safe and efficacious treatment option for breast fibroadenoma.
- Results suggest positive outcome of the ongoing pivotal trial of Echopulse® for non-invasive treatment of breast fibroadenomas.

Malakoff - FRANCE, November 20, 2017 - THERACLION (Euronext Growth, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced the presentation of data from the U.S. pilot trial of echotherapy with Echopulse®, a non-invasive treatment using ultrasound-guided high-intensity focused ultrasound (HIFU), in women with breast fibroadenomas. Results will be presented at the Radiological Society of North America (RSNA) Annual Meeting that will be held from November 26 to December 1, 2017, at the McCormick Place in Chicago (USA). Theraclion also announced its participation to the RSNA as an exhibitor to present the Echopulse® system on booth #4475 in the French Pavilion.

The podium presentation will be done by Carrie M. Rochman, M.D., Assistant Professor of Radiology in the Department of Radiology and Medical Imaging from the University of Virginia (USA) member of David Brenin' team, MD, Chief of Breast Surgery, co-director of the University of Virginia Breast Care Program, Associate Professor of Surgery at UVA's School of Medicine and principal investigator of the ongoing pivotal trial. The talk, entitled *"Ultrasound Guided High Intensity Focused Ultrasound Ablation of Breast Fibroadenoma: A Pilot Study"* will take place on Wednesday, November 29 within the "Breast Imaging (Intervention Path Correlation)" session from 10:30-12:00 PM in Room E450A.

The single-arm pilot study, IRB and FDA approved, enrolled 20 patients with 1 cm or larger palpable breast fibroadenomas to assess the safety, feasibility and efficacy of echotherapy in the treatment of breast fibroadenomas. The study showed that mean reduction in volume of the fibroadenoma at 12 months after echotherapy was 65%, mass being no longer palpable in 80% of patients. The procedure was well-tolerated without neither skin burns, damage to adjacent structures, nor other major toxicities. Mild pain was the most commonly-reported side effect. Patient satisfaction after three months was 4.4 (scale of 1-5, in which 5 indicated most satisfied).

Following this initial feasibility study, Theraclion has recently launched a U.S. pivotal trial evaluating the safety and efficacy of Echopulse. Over 25% of patients have already been treated in this pivotal trial. The trial will enroll approximately 100 patients at four centers in the U.S., University of Virginia School of Medicine, NYU Langone Bellevue, Montefiore Medical Center (NY) and New York-Presbyterian/Columbia University Medical Center and two in Europe with Tübingen University Hospital, Germany and the University Hospital of Endocrinology in Sofia, Bulgaria. Further information about the trial can be found at Clinical Trial.

Dr. Brenin said, "*Today, the only treatment for fibroadenoma without focused ultrasound ablation is surgery. The main advantage of focused ultrasound ablation for the treatment of fibroadenoma is that it avoids surgery. As there is no surgery, there is no scar, and recovery from the procedure is much*

faster, i.e. a few hours instead of a few days. Data showed that treatment with the echotherapy device is well-tolerated by patients with minimal discomfort. Reduction in the size of the palpable mass was reported by both the patient and evaluating team in all cases. All patients reported that they would recommend the procedure to a friend or family member."

Michel Nuta, MD, Chief Medical Officer of Theraclion, added, *"The results of this trial are consistent with clinical evaluations performed in Europe and further validate our technology as an exciting alternative to treat breast fibroadenomas. Echopulse is currently indicated with a CE Mark in Europe as the only HIFU solution for this condition. In the U.S., we continue to enroll patients in our U.S. pivotal trial, for which we anticipate completing and announcing top-line results in 2019."*

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
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Contacts :

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

Kalima
Relations Presse
Marie Vasseur
Tel.: + 33 (0)1 42 21 56 36
mvasseur@kalima-rp.fr