



THERACLION announces presentation of U.S. clinical data supporting Echotherapy with Echopulse® for breast fibroadenomas at The American Society of Breast Surgeons (ASBrS) Annual Meeting

- Echotherapy was well-tolerated and resulted in minimal side effects.
- Results suggest positive outcome of the ongoing pivotal trial of Echopulse® for non-invasive treatment of breast fibroadenomas.

Malakoff - FRANCE, May 02, 2017 - THERACLION (Alternext, FR0010120402 - ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced the presentation of data from the U.S. feasibility trial of echotherapy with Echopulse®, a non-invasive treatment employing ultrasound-guided high-intensity focused ultrasound (HIFU), in women with breast fibroadenomas. Results were presented at [The American Society of Breast Surgeons \(ASBrS\)](#) Annual Meeting, held April 26 – 30 in Las Vegas, NV.

The single-arm feasibility study was led by David Brenin, 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 study enrolled 20 patients with 1 cm or larger palpable breast fibroadenomas to assess the safety and feasibility of a single Echopulse treatment. Fifty percent of patients reported a painful mass prior to enrollment. The study showed that echotherapy was well-tolerated. Pain and discomfort were the most commonly-reported side effects but remained minimal. Patient satisfaction after three months was 4.4 and the likelihood that they would recommend the treatment to a friend or family member was 4.7 (scale of 1-5, in which 5 indicated most satisfied). Long-term cosmetic outcome, reduction in breast fibroadenoma size and patient experience are currently under investigation.

Following this initial feasibility study, Theraclion has recently launched a U.S. pivotal trial evaluating the safety and efficacy of Echopulse. The pivotal trial is currently enrolling patients and is also being led by Dr. Brenin. 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, *“Although benign, breast fibroadenomas can cause discomfort, and the discovery of a lump in their breast can create anxiety in women. The current standard of care is surgery, which can cause significant pain and discomfort requiring medication and inevitably leads to scar formation.*

Echopulse is a very promising non-invasive alternative approach to treat the condition without the complications of surgery.”

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 34 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 Alternext Paris

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