



First Data Generated in U.S. Support Theraclion's Echotherapy System

Echopulse Achieved Positive Clinical Results in 5 Studies from U.S., Europe and Asia for the Treatment of Breast Fibroadenoma and Benign Symptomatic Thyroid Nodules

FDA Provides Clearance to Initiate 100-Patient IDE Study for Breast Fibroadenoma

Malakoff, FRANCE – August 31, 2016 – THERACLION (Alternext, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced data from five studies demonstrating that echotherapy continues to show very promising clinical results. Results were presented this week at the [5th International Symposium on Focused Ultrasound](#) (FUS), held August 28 – September 1, 2016 in Bethesda, USA. Theraclion also announced that the U.S. Food and Drug Association (FDA) cleared Theraclion's request for an Investigational Device Exemption (IDE) for breast fibroadenoma, which will be developed via the 513(f)(2) pathway.

Hosted by the Focused Ultrasound Foundation, the International Symposium on Focused Ultrasound is the single most significant international conference dedicated to high-intensity focused ultrasound (HIFU) therapy, bringing together every year the leading experts, researchers and practitioners in the field, alongside key players in the industry.

"Results from the presented studies continue to demonstrate the very good efficacy and tolerability of echotherapy (US-guided High Intensity Focused Ultrasound - HIFU) as a non-invasive ablative technique for both symptomatic breast fibroadenoma and benign symptomatic thyroid nodule indications," commented Michel Nuta, M.D., Chief Medical Officer of Theraclion.

David Caumartin, CEO of Theraclion added, "Through additional clinical trials, including now in the U.S., we believe we will continue to demonstrate the value of the Echopulse® system for physicians and their patients."

As part of this year's FUS symposium, the latest results were presented from three studies on the treatment of breast fibroadenoma and two on the treatment of thyroid nodules.

- **Carrie Rochman, M.D., Assistant Professor of Radiology, under principal investigator Dr. David Brenin, M.D., FACS, Chief of Breast Surgery, Co-director of the University of Virginia Breast Care Program and Associate Professor of Surgery at UVA's School of Medicine**, presented the first U.S. results of treatment with Echopulse® with preliminary findings from an ongoing, single arm, feasibility study (HIFU-FA-001) of 20 female patients diagnosed with palpable breast fibroadenomas (BFAs). Sixteen patients were treated to date. All reported that they would recommend the procedure to a friend or family member. Reduction in the size of the palpable mass was reported by both the patient and evaluating physician in all cases. Data showed that treatment with Echopulse® was well-tolerated by patients with minimal discomfort. There have been no grade 3 adverse events, no skin burns, no persistent changes in skin appearance, and no other significant toxicities/morbidities observed. (Abstract ID: CA-44)



- **Michael Douek, M.D., Professor of Surgical Oncology and Breast Surgeon**, presented interim results to date of an ongoing, single-arm study (HIFU-F) of 50 female patients diagnosed with symptomatic, palpable breast fibroadenoma. Interim results demonstrated that circumferential HIFU ablation of fibroadenoma with Echopulse® is feasible, with a significant reduction in volume compared to control patients, and provided a simple, non-invasive, outpatient-based alternative management option for the condition. For the 20 patients treated with Echopulse® in the study to date, results showed a significant mean reduction in fibroadenoma volume of 43.5%, compared to a 4.6% reduction in volume observed in the control group at six months. Circumferential ablation significantly reduced the mean treatment time by 37.5% compared to whole lesion ablation. In addition, six of eight patients who experienced pre-treatment pain had complete resolution of symptoms six months post-treatment. (Abstract ID: CA-46)
- **Brian Lang, M.D., Clinical Associate Professor of the University of Hong Kong and Chief of Endocrine Surgery of Queen Mary Hospital and Tung Wah Hospital**, presented results of an ongoing, prospective, single-arm study of 22 patients with benign symptomatic thyroid nodules. Results demonstrated that ultrasound-guided HIFU ablation with Echopulse® is an effective and safe treatment option for patients with benign symptomatic thyroid nodules and has the potential to improve the health-related quality of life of patients who do not wish to undergo surgical resection. Of the 22 patients treated with Echopulse® at six months following echotherapy, the average treated nodule volume reduction was 71.58% ± 11.81%. The study also showed a significant improvement in all quality-of-life domains, including sleep quality, daytime sleepiness, mood state, anxiety, depression, as well as the physical component of the SF-12 Physical and Mental Health Summary Scale. (Abstract ID: CA-50)
- **Roussanka Kovatcheva, M.D., Professor of Endocrinology at the University Hospital of Endocrinology of Sofia, Bulgaria**, presented highly promising results from two studies:
 - An ongoing, prospective, single-arm study of 20 patients evaluating the long-term efficacy and tolerability of treatment of breast fibroadenoma with Echopulse®. The results showed that fibroadenoma volume decreased significantly at one-month and three-month follow-up, respectively, and continued to decrease at 24-month follow-up. At 24 months, mean volume reduction was 77.32% in group 1 (1 echotherapy session) and 90.47% in group 2 (two echotherapy sessions). (Abstract ID: CA-45)
 - An ongoing, single-arm study of patients with thyroid nodules, showed that the mean percent of volume reduction at three months and at 12 months after echotherapy were 47.4% ± 20.8% and 55.5% ± 28.4%, respectively, in group 1 (only one session) and were 24.2% ± 15.8% and 46.0% ± 22.0%, respectively, in group 2 (two sessions). (Abstract ID: CA-51)



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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