



New Clinical Data Strongly Support the Safety and Efficacy of Theraclion's Echotherapy System

- *Publication of first comparative study demonstrates positive mid-term results with Echopulse®*
- *New results presented at ETA and CIRSE 2016*

Malakoff, FRANCE – September 26, 2016 – THERACLION (Alternext, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced the results of a study published in the September issue of the *International Journal of Hyperthermia*. The data are a mid-term assessment of breast fibroadenoma volume and pain following circumferential treatment with Theraclion's Echopulse®. Theraclion also announced results from two studies collectively demonstrating that Echopulse® high intensity focused ultrasound (HIFU) technology effectively reduces thyroid nodule volume and appears to be safe and well-tolerated. These data were presented at the [39th Annual Meeting of the European Thyroid Association \(ETA\)](#) in Copenhagen and [Cardiovascular and Interventional Radiological Society of Europe \(CIRSE\) 2016 Congress](#) in Barcelona.

Positive mid-term results in *International Journal of Hyperthermia*

The study, entitled "[High intensity focused ultrasound in the treatment of breast fibroadenomata: results of the HIFU-F trial](#)," demonstrated the effectiveness of Echopulse® in the circumferential treatment of breast fibroadenoma compared to an observational cohort. Conducted by Professor Michael Douek's team in the Breast Surgery department of Guy's and St. Thomas University Hospital, London, UK, the study evaluated 40 patients with breast fibroadenoma; 20 were treated circumferentially with Echopulse® HIFU compared to 20 receiving watchful waiting. All patients were assessed before the treatment performed with Echopulse® and after the end of follow-up period.

Results of the study showed that:

- Breast fibroadenoma volume was significantly reduced by 43.5% after the echotherapy procedure;
- Mean volume reduction between the two groups was significantly in favor of the echotherapy (HIFU) group;
- Pre-treatment pain was completely resolved in 75% of echotherapy patients;
- Circumferential ablation reduced the mean treatment time by 37.5% compared to the standard protocol;
- Circumferential ablation is feasible, and is a simple, non-invasive, outpatient based alternative to surgical excision;
- In terms of safety, no serious side effects related to the procedure were reported, in line with the acute observations.



Michel Nuta, M.D., Theraclion Chief Medical Officer, said: *“The results of this trial confirm the efficacy of circumferential treatment for the indication of breast fibroadenoma with significant treatment time reduction. In addition, for the first time, comparative results versus a control group are available and reinforce the quality of the outcomes previously published in un-controlled cohorts. We are continuing our clinical research programs for establishing Echopulse® as a modern standard of care.”*

Results presented at ETA and CIRSE 2016 confirm safety and efficacy of Theraclion’s echotherapy system for the treatment of thyroid nodules.

“Our Echopulse® echotherapy system is on the market in Europe and Asia and is in clinical development in the U.S. as a non-invasive option to treat both thyroid nodules and benign breast fibroadenomas,” commented David Caumartin, CEO of Theraclion. *“Results of studies presented at the ETA and CIRSE Annual Meetings, as well as previously-conducted studies, continue to demonstrate the efficacy of echotherapy in treating benign thyroid nodules without surgery and with a promising safety profile.”*

At ETA, Roussanka Kovatcheva, M.D., Professor of Endocrinology at the University Hospital of Endocrinology of Sofia, Bulgaria presented results of a prospective, single-arm study of 15 patients with benign solid thyroid nodules treated with Echopulse®. Results demonstrated US-guided ablation with Echopulse® effectively reduces thyroid nodule volume and unlike surgical approaches, has only transient influence on thyroid function. The mean nodule volume decreased significantly by 27.7±17.3% at 3 months. Overall, the increase of thyroglobulin and the decrease in serum and hormone levels (TSH, FT3, FT4) occurred following the HIFU procedure, but returned to baseline, indicating that thyroid function was restored to normal values following the procedure.

At CIRSE, Prof. Kovatcheva presented results of a 20-patient, prospective, dual-arm study [previously presented at the 5th International Symposium on Focused Ultrasound \(FUS\)](#) in Bethesda, USA. Researchers concluded that the effect of one and two consecutive HIFU treatments using Echopulse® in solid benign thyroid nodules is comparable, and that the method is safe and well tolerated by the patients, with rare and transient side effects. They found that long-term thyroid function remains normal.

About ETA

The European Thyroid Association aims to promote knowledge in the thyroid field and improve knowledge of the thyroid gland and its diseases. The Annual Scientific Meeting attracts more than 350 abstracts and more than 900 attendees.

About CIRSE

The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) aims to improve patient care through the support of teaching, science, research and clinical practice in the field of cardiovascular and interventional radiology. Interventional radiology is an innovative and ever-expanding specialty that provides minimally invasive treatments for a wide range of diseases, which are performed by specially trained physicians using imaging techniques such as X-ray, CT, MRI and ultrasound for guidance. Approximately 6,500 people attended the congress.



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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