



THERACLION reports publication of promising clinical trial results in a new thyroid indication

The study evaluates the efficacy of Echopulse® in the treatment of Graves' disease

Published in "Radiology", the study reports the treatment and follow up of 30 patients. It concludes:

- A remission rate at 12 months equal to 73.3% (suppression of hyperthyroidism),
- A significant decrease in the titers of autoantibodies (anti TSHr),
- No alteration of other anti-thyroid antibody levels nor ophthalmic parameters,
- The feasibility and probably favorable cost effectiveness compared to surgery for all patients who received the single session, bilateral procedure (one patient required two sessions).

Malakoff - FRANCE, August 29th, 2017 - THERACLION (Alternext, FR0010120402 - ALTHE, PEA PME eligible), a company specialized in leading-edge medical equipment for echotherapy, today announces the results published in the « **Radiology** » journal on Graves' disease treatment by echotherapy using Echopulse. The study is entitled: *"Single-Session High-Intensity Focused Ultrasound Treatment for Persistent or Relapsed Graves' Disease: Preliminary Experience in a Prospective Study"* and is available [online on PubMed](#).

Graves' disease (GD) is an autoimmune thyroid disorder caused by the presence of autoantibodies stimulating the TSH receptor. It is the most common cause of hyperthyroidism and approximately 3% of women and 0.5% of men develop GD in their lifetime. In many parts of the world, anti-thyroid drugs (ATD) have been the preferred initial treatment for GD. However, once a patient remains or continues to be hyperthyroid after an 18-month or longer course of ATDs, definitive treatments such as surgery or radioactive iodine therapy are generally recommended. Nevertheless, a substantial proportion of patients prefer to continue receiving ATDs instead of proceeding to surgery or RAI therapy because of surgical risks and radiation fear. Theraclion estimates that the availability of a non-surgical, non-radioactive approach to treat persistent or recurrent hyperthyroidism has the potential to expand volume of thyroid procedure by 40% compared to current indication to treat benign thyroid nodules.

This series of cases was performed and assessed by Dr. Brian Hung-Hin LANG, MD, Clinical Associate Professor, Department of Surgery, Chief of the Endocrine Surgery Division at the Queen Mary University Hospital in Hong Kong.

A group of thirty consecutive patients with persistent or relapsed GD treated between November 2015 and February 2016 was examined for thyroid function at baseline, at 2 and 4 weeks and 2, 4, 6, 8, 10 and 12 months following the treatment performed by Echopulse and clinically assessed at the same time.

The article published in the prestigious US journal “Radiology” demonstrates very promising Echopulse post-treatment results confirmed by hormonal profile and clinical assessment. The patients treated with Echopulse showed at 12 months follow-up:

- An overall remission rate of 73,3%, which means a relief from hyperthyroidism,
- A significant decrease in the autoantibodies (anti TSHr),
- Absence of complications in terms of ophthalmic parameters and anti-thyroid antibody levels evolution.
- In 96,7% of the cases, patients completed the echotherapy treatment within one session and were discharged on the day of the treatment. This would imply superiority in terms of cost effectiveness compared to surgery.

Pr Brian LANG, MD, principal investigator, comments: “US-guided HIFU ablation of the thyroid may be a safe and efficacious treatment in patients with persistent or relapsed GD, offering patients an alternative to invasive surgery or radioactive iodine, a treatment which many patients refuse, especially in Asia.”

Sylvain Yon, Deputy CEO & VP Research & Development of Theraclion, concludes: “Theraclion continues the development of new indications, pioneering non-invasive ultrasound treatment as an alternative to surgical procedures and radioactive iodine treatment. Just as the breast cancer FDA trial authorization, these first results are extremely encouraging, and could add another indication to the panel of indications Echopulse can treat, which would be welcomed by our current as well as future Echopulse users.”

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, half of it 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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