



## Theraclion presents positive results in two studies published in *Radiology* and in the *Journal of Therapeutic Ultrasound*

### Demonstration of Echopulse® efficacy in the treatment of benign thyroid nodules

- Ablation effectiveness proved by significant thyroid nodule volume reduction after 3- to 6-month follow-up
- Well tolerated procedure preserving skin integrity and thyroid function
- Results achieved after a single treatment session and with higher efficacy in less vascularized nodules

**Malakoff – FRANCE, March 16, 2015 – THERACLION** (Alternext, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, announces today the results published on March 2015 in *Radiology* and in the *Journal of Therapeutic Ultrasound* on the mid-term assessment by nodular volume reduction of benign thyroid nodules treated with Echopulse®:

- **Radiology:** *US-guided High-Intensity Focused Ultrasound Ablation of Benign Solid Thyroid Nodules: Initial Clinical Outcomes* is available online: <http://pubs.rsna.org/doi/full/10.1148/radiol.15141492>
- **Journal of Therapeutic Ultrasound:** *Volume reduction of benign thyroid nodules three months after a single treatment with High Intensity Focused Ultrasound (HIFU)* is available online: <http://www.jtultrasound.com/content/3/1/4/abstract>

These studies – the first conducted on twenty benign thyroid nodules and the second on ten benign thyroid nodules – were performed and assessed by Prof. Roussanka Kovatcheva, MD, PhD and her team (Department of Thyroid and Metabolic Bone Disorders, University Hospital of Endocrinology, Sofia, Bulgaria) and by PD Dr. Huedayi Korkusuz, Associate Professor and member of the team of Professor Grünwald (Nuclear Medicine Department and German Center of Thermoablation of Thyroid Nodules, Goethe University Clinic, Frankfurt am Main, Germany). All patients in these two studies were assessed by nodule volume determination before the treatment with Echopulse® and at the end of the follow-up period (between three and six months).

The article published in the prestigious American journal *Radiology*, demonstrates consistent Echopulse® postoperative results that are confirmed at mid-term by the nodule volume assessments. The patients treated with Echopulse® demonstrated:

- Significant mean thyroid nodule volume reduction of 48.7% six months after the procedure ( $p < 0.01$ )
- Maximum volume shrinkage of 93% from baseline

- Significant decrease (from 2.6 to 1.9 -  $p=0.022$ ) in the cosmetic score and significant increase in the satisfaction score (8.8 from 10), confirming the treatment's effect and the patient's approval
- Excellent tolerability with only minor transient side effects (lasting from 1 week to 1 month) observed in two patients

The article published in the *Journal of Therapeutic Ultrasound* demonstrates that consistent Echopulse® postoperative results were obtained at mid-term, based on assessment of nodule volume. More specifically, in patients treated with Echopulse®:

- Thyroid nodule volume was significantly reduced by a median of 48.8% three months after the procedure ( $p<0.05$ ),
- Nodule volume shrinkage of up to 75% was observed, witnessing a major ablation success after a relatively short follow-up period,
- One single treatment session was sufficient to reach these results,
- Thyroid function was preserved.

In terms of safety, no serious side effects related to the procedure were observed during three months of follow-up, in line with the immediate follow-up observations.

**Prof. Roussanka Kovatcheva, Principal Investigator, comments:** *“Our study demonstrated that a single procedure with Theraclion Echopulse® induced significant volume reduction in benign thyroid nodules with favorable cosmetic and safety outcomes. It is a method that avoids interruption of skin integrity, without penetration of the treatment device into the nodule, and causes fewer side effects and no risk of bleeding.”*

**PD Dr. Huedayi Korkusuz, Associate Professor, adds:** *“The advantages of this method are its non-invasiveness, the low infection risk and the absence of scars. Combined with the efficacy demonstrated by the studies, it is a method which is particularly attractive for our patients.”*

**Michel Nuta MD, Theraclion Chief Medical Officer, concludes:** *“These relevant and significant results confirm the efficacy, the durability and the degree of persistence of the outcomes obtained with our method. The good tolerance, the treatment efficacy and the cosmetic advantage are substantial additional benefits for the patients. We will continue to improve our method for an optimal patient-friendly approach and continue our assessment at longer term follow-up.”*

**About Theraclion**

Based in Malakoff, near Paris, Theraclion is a French company specialized in leading-edge medical devices for echotherapy. Theraclion designs, develops and markets a medical device (Echopulse®) that combines advanced ultrasound imaging and HIFU therapy. Theraclion is ISO 13485 certified and has received the CE mark for non-invasive ablation of breast fibroadenomas and thyroid nodules. A full 65% of its 23-strong team are dedicated to R&D and clinical trials. For more information, visit <http://www.theraclion.com>.

**Theraclion is listed on Alternext Paris**

**Mnemonic: ALTHE - ISIN Code: FR0010120402**

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