



First international, multicentric study to present long-term results of echotherapy in breast fibroadenoma

Theraclion announces study showing long-term effectiveness and safety of Echopulse® in the non-invasive treatment of breast fibroadenoma:

- Ablation effectiveness proven by significant breast fibroadenoma volume reduction at 6 and 12-month follow-up
- Persistent decrease in fibroadenoma volume for all cases. No ultrasound evidence of regrowth
- Symptoms reduction with pain and discomfort related to fibroadenoma completely resolved at the end of the follow-up
- High patients' satisfaction with excellent cosmetic results
- Well tolerated procedure with no serious adverse events

Malakoff - FRANCE, February 12, 2015 - THERACLION (Alternext, ISIN: FR0010120402 – Ticker: ALTHE), a company specialized in leading-edge medical equipment for echotherapy, announces today the results published end January, 2015 in the “Journal Therapeutic Ultrasound” on the long-term assessment of breast fibroadenoma following treatment with Echopulse®. The publication “*Ultrasound-guided high-intensity focused ultrasound treatment of breast fibroadenoma – a multicenter experience*” is available online: <http://www.ncbi.nlm.nih.gov/pubmed/25635224>.

This multicenter study on fifty-one breast fibroadenoma was performed in four centers in Bulgaria and in France (Roussanka Kovatcheva MD - Medical University of Sofia, Jean-Noel Guglielmina and Marc Abehsera MD - American Hospital of Paris, Loic Boulanger MD - University Hospital of Lille, and Nicolas Laurent and Edouard Poncelet MD - Regional Hospital of Valenciennes).

Forty-two patients with fifty-one fibroadenoma were assessed before the echotherapy treatment performed with Echopulse® and after the end of follow-up period.

The article published in the “Journal of Therapeutic Ultrasound” demonstrated consistent results confirmed at one year. The patients treated with Echopulse® showed:

- that the breast fibroadenoma volume was significantly reduced by 59.2% (mean) 6 months after the procedure ($p < 0.001$) and by 72.5% ($p < 0.001$) at the 12-month follow-up,
- a continuous improvement of discomfort in daily activities as well as of the pain related to the breast fibroadenoma during follow up until total disappearance,
- excellent cosmetic results without scar formation or breast volume loss,
- excellent tolerance with minor transient complications which resolved spontaneously.

In terms of safety, no serious side effects related to the procedure were reported, in line with the acute observations.

Roussanka Kovatcheva MD and Principal Investigator, comments in her article: *"We have shown the clinical outcome and safety of US-guided HIFU (High Intensity Focused Ultrasound) by Theraclion Echopulse® in patients with breast FA. Our results demonstrated that the method is effective in reducing the volume and clinical symptoms of FA without serious side effects. US-guided HIFU is a non-invasive alternative to surgery."*

Marc Abehsera MD, Radiologist at the American Hospital of Paris and Investigator, says: *"The presented results are extremely encouraging and confirm the Echopulse system's capabilities could be an effective alternative to surgery for breast fibroadenoma."*

Michel Nuta MD, Theraclion Chief Medical Officer, concludes: *"The results of this international multicenter trial confirm the efficacy, the durability and the degree of persistence of echotherapy in breast fibroadenoma. While we continue to foster clinical investigation, we believe that echotherapy will be the future standard of care."*

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 23 people, 65 percent 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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