THERACLION reports positive long-term Echopulse® results in breast fibroadenoma

- Mean volume reduction at 24 months:
  - 77% (small volumes fibroadenoma: treatment in single session)
  - 90% (larger volumes: treatment in 2 sessions)
- Volume reduction is maintained at 24 months following treatment with no evidence of recurrence
- Treatment is safe and well-tolerated by patients

Malakoff - FRANCE, April 06, 2017 - THERACLION (Alternext, FR0010120402 - ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced results of a study evaluating the long-term assessment of breast fibroadenoma (benign tumor) volume reduction following treatment with the company's Echopulse®, a non-invasive treatment employing ultrasound-guided high-intensity focused ultrasound. The study, entitled "Long-term efficacy of ultrasound-guided high-intensity focused ultrasound (US-guided HIFU) treatment of breast fibroadenoma," was published online in the March 2017 issue of the *Journal of Therapeutic Ultrasound* and is available online: https://jtultrasound.biomedcentral.com/articles/10.1186/s40349-017-0083-1

The study assessed a total of 20 female patients with 26 breast fibroadenomas (BFAs) before and for up to 24 months following echotherapy treatment with Echopulse®. 19 BFAs received a single treatment and seven BFAs a second treatment six to nine months after the initial session. BFA volume was measured by ultrasound. Patient satisfaction on cosmetic results and symptom relief were surveyed and safety and tolerability was recorded.The study demonstrated consistent echotherapy results confirmed at 24 months:

- Mean BFA volume was significantly reduced by 77.32% after a single procedure and by 90.47% after two procedures at 24 months follow up;
- No cases of re-growth of treated lesions were observed during the 24 months follow-up;
- Treatment was very well-tolerated regardless of whether one or two echotherapy sessions were performed; side effects were mild and transient and resolved completely; no serious side effects were observed;
- Of the 20 patients who completed a satisfaction survey, all 20 (100%) were completely or highly satisfied with the cosmetic results and 19 of 20 (95%) were completely or highly satisfied concerning symptom disappearance;
- Authors concluded that "US-guided HIFU represents a promising non-invasive method with sustainable FA volume reduction and patient's tolerability. Although one treatment is highly efficient, the volume reduction can be increased with second treatment."

Pr. Roussanka Kovatcheva M.D., Professor of Endocrinology at the University Hospital of Endocrinology of Sofia, Bulgaria, and Principal Investigator said, *"Our results show the long-term efficacy and safety of US-guided HIFU generated by Theraclion's Echopulse® in patients with breast fibroadenomas. US-guided HIFU is definitely an effective non-invasive alternative to surgery enabling more than 90% volume reduction without re-growth or serious adverse events."*

Michel Nuta MD, Chief Medical Officer of Theraclion, added, *"The results of this trial provide validation and confirmation of the remarkable and enduring effect of the Echopulse® treatment for the breast fibroadenoma indication. In addition, for the first time, results related to the incremental efficacy of a second echotherapy session, with absence of rebound or serious adverse effects, were assessed at a significant follow-up period of two years. We are continuing our clinical research programs, including a 100-patient trial in the U.S., for reinforcing the status of Echopulse® as a proven and patient friendly 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 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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