



THERACLION announces presentation of results in benign and malignant breast tumors

- University of Virginia presents clinical update on breast cancer combination study with immunotherapy and new study on benign breast tumors at the Focused Ultrasound Foundation Symposium, Virginia, USA
- University of Tübingen publishes “No vital cell presence in 86% of the cases” in Journal of Hypothermia

Malakoff, October 24th, 2018 – THERACLION (Euronext Growth, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, announces today the presentation of results of two clinical studies at the Focused Ultrasound Foundation Symposium (FUS) held October 24 as well as the results published on September 11th, 2018 in the « International Journal of Hyperthermia » on the treatment by Echopulse® of benign and malignant breast tumors.

The FUS podium presentation introduced the rationale for a combination therapy study of High Intensity Focussed Ultrasound (HIFU, also called echotherapy) with immunotherapy in breast cancer: HIFU is a partially ablative therapy using high energy ultrasound waves to induce a heat shock to proteins, cytokine release and cellular mediated mechanisms resulting in T cell activation and recognition of tumor antigens. HIFU has been demonstrated to be an effective method for inducing tumor antigen exposure and presentation to dendritic cells, thus acting as an auto-vaccine. The immunotherapy drug Pembrolizumab (PBZ) is a PD-1 targeted antibody used in multiple solid tumors to augment T cell activation. The combination of these two modalities may result in T cell infiltration into breast tumors as well as systemic immune responses.

“With only 22% survival at 5 years, there are no curative therapies for women with stage IV disease” explains Michel Nuta, CMO Theraclion, “immunotherapy brings new hope for other types of cancer but is not very effective in breast cancer, because the immune system does not recognize most breast cancers as “not self.” White blood cells are not attracted to most breast cancer tumors. This is what echotherapy can change: Echotherapy initiates a brisk local immune response due to cellular injury and dysfunction and thereby ‘recruits’ white blood cells to traffic to, and infiltrate into the damaged area of the tumor. Now immunotherapy can take the brake off those blood cells and attack the tumor.”

“I am excited to have designed this pilot study combining focused ultrasound therapy with pembrolizumab for women with metastatic breast cancer because I believe it has the potential to instruct the cancer therapy field in both the local and systemic immune responses to this novel combination.” Says Patrick Dillon, MD, Assistant Professor of Oncology of the University of Virginia Cancer Center “I am hopeful that we will observe some degree of clinical benefit as well as learn about the immune impacts of these therapies. The study is a pilot study so we hope to be able to draw conclusions about safety and immune activity of this combination of FUS and pembrolizumab. We are actively looking for recruiting new patients in the study.”

Also disclosed during the FUS Symposium were the results of the new study demonstrating safety and



the efficacy of Echopulse® in the treatment of symptomatic Breast Fibroadenoma. HIFU effectiveness in breast fibroadenoma was validated by post treatment core needle biopsy and showed an important volume reduction of the benign lump. The ambulatory procedure was reported to be well tolerated, simple and non-invasive under local anesthesia.

Theraclion also announces the publication of a study entitled: High intensity focused ultrasound (HIFU) for the treatment of symptomatic breast fibroadenoma is available online: <https://www.tandfonline.com/doi/full/10.1080/02656736.2018.1508757>.

This study on 27 cases was performed and assessed by Pr. Markus Hahn, MD, Frauenklinik - University Hospital Tübingen, Germany).

Twenty-seven patients with breast fibroadenoma, examined up to 12 months after the procedure, were assessed by ultrasound and histology before and after the treatment performed by Echopulse®.

The article published in a journal specialized in new thermic methods reviews, demonstrates that the Echopulse® postoperative results are confirmed by histology. The patients treated with Echopulse® showed:

- No vital cell presence in 86% of the cases as per the core needle biopsy performed 12 months after the procedure
- A mean volume reduction of 84.8% at the end of follow-up.
- A 100% satisfaction rate with cosmetic results.
- An easy to perform ambulatory procedure, exclusively under local anesthesia.

In terms of safety, no serious side effect related to the procedure was reported and only one treatment session per patient treatment was necessary.

Pr Markus HAHN, MD, principal investigator, comments in his article: *“HIFU represents the next logical step to a non-invasive, well-tolerated and efficient method with the lowest side effect possible rate and without any risk of infection. Based on the results of this study with Theraclion’s Echopulse® there is objective evidence by biopsy confirming the high efficacy of the method. Thus, HIFU constitutes an interesting alternative to surgery. This treatment could, in the near future, be an option for breast cancer patients.”*

Michel Nuta MD, Theraclion Chief Medical Officer, concludes: *“These objective results confirmed by histology are definitely proving the efficacy of the method and the potential absence of recurrence. This is accompanied by a remarkable improvement for patient’s quality of life, with complete satisfaction in terms of esthetic outcomes.”*

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, 50% of whom are dedicated to R&D and clinical trials. For more information, please visit Theraclion’s website: www.theraclion.com



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