



THERACLION reports first presentation of results for breast cancer strategy

Encouraging, initial immunotherapy combination trial results presented at ASCO-SITC meeting in San Francisco

Malakoff - FRANCE, January 24th, 2018 - THERACLION (Alternext, FR0010120402 - ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced that Dr. Patrick M. Dillon, MD, UVA Medical Center, Charlottesville, USA, primary investigator of the echotherapy/immunotherapy combination trial has presented data on echotherapy in combination with immunotherapy at the ASCO (American society of clinical oncology)-STIC (Society for immunotherapy of cancer) clinical immuno-oncology symposium taking place (<https://immunosym.org>) on January 25th in San Francisco, USA.

There were 252,710 new cases of breast cancer in the United States in 2017, which represents the most common cancer (excluding non- melanoma skin cancers). Breast cancer is the second leading cause of cancer death, with 40.000 deaths annually. Breast Cancer is the leading overall cause of death for women aged 40 - 55.

The scientific poster introduces the rationale for the combination therapy study: FUS is a partially ablative therapy using high energy ultrasound waves to induce heat shock proteins, cytokine release and cellular mediated mechanisms resulting in T cell activation and recognition of tumor antigens. FUS has been demonstrated to be an effective method for inducing tumor antigen exposure and presentation to dendritic cells, thus acting as an auto-vaccine. Pembrolizumab (PBZ) is a PD-1 targeted antibody used in multiple solid tumors to augment T cell activation. It is hypothesized that the combination of these two modalities will 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 Dr. Dillon “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.”

The phase I clinical trial is actively recruiting patients:

- 4 patients are enrolled to date.
- No adverse safety signal to date for the ultrasound partial tumor ablations in combination with pembrolizumab.
- The most frequent side effects so far are limited to ablation site pain, fatigue, nausea and dyspnea.

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 35 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 Euronext Growth Paris

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Mnemonic: ALTHE - ISIN Code: FR0010120402



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