



UVA Cancer Center to expand use of Theraclion's HIFU system in cancer treatment research.

Malakoff, June 1st 2021 - THERACLION (ISIN: FR0010120402; Mnemo: ALTHE, PEA-PME eligible), an innovative company specialized in echotherapy treatment (using High Intensity Focused Ultrasound or HIFU), announces a phase-2 collaboration with the University of Virginia Cancer Center. This extends the investigation of combining HIFU with immunotherapy from late-stage to that of early-stage breast cancer. If successful, such a protocol could open a new way for treatment. An estimated 3.8 million women have a history of breast cancer in the US¹.

After an initial successful collaboration, the University of Virginia (UVA) Cancer Center has extended the use of Theraclion's world-class technology to a phase-2 investigation. This further collaboration includes the sale and servicing for 3 years of their current Echopulse system used for research in breast tumour treatment. It includes un-limited usage for 3 years to support all investigations.

Patrick Dillon, Associate Professor in the department of Oncology and David Brenin, Professor in diseases of the breast and Chief of the Division of Breast and Melanoma Surgical Services at University of Virginia, said: "We look forward to working in collaboration with Theraclion to conduct research on the efficacy of the combination of focused ultrasound ablation and immune therapy as a potential treatment for patients with breast cancer. We are excited to continue to work to improve the efficacy, precision, and safety of this potential approach."

Promising clinical study in progress

UVA researchers have investigated the potential application of Theraclion's technology, using focused ultrasound (FUS) to overcome the limitation of the accessibility of immunotherapies to tumors due to poor T cell infiltration and mechanisms of adaptive resistance is known. Based on positive results on murine mammary carcinoma², a pilot clinical study has been initiated³ to evaluate the use of HIFU combined with pembrolizumab in patients with metastatic breast cancer. The study tested the hypothesis that FUS thermal ablation can serve as an auto-vaccine for treatment of BRCA with immunotherapy on patients with confirmed metastatic or unresectable breast cancer. Final results should be shared in few months, but the study has shown promising properties of HIFU on breast tumors. This has encouraged the UVA research team to further investigate the potential benefits of HIFU.

¹ Howlader N, Noone AM, Krapcho M, et al., eds. SEER Cancer Statistics Review, 1975-2016. Bethesda, MD: National Cancer Institute; 2019. Available from seer.cancer.gov/csr/1975_2016/, based on November 2018 SEER data submission, posted to the SEER web site April 2019.

² Perspectives on Recent Progress in Focused Ultrasound Immunotherapy Natasha D. Sheybani and Richard J. Price

³ Focused Ultrasound Therapy to Augment Antigen Presentation and Immune-Specificity of Checkpoint Inhibitor Therapy with Pembrolizumab in Metastatic Breast Cancer Focused Ultrasound and Pembrolizumab in Metastatic Breast Cancer - Full Text View - ClinicalTrials.gov



New study focused on treatment of early-stage breast cancer

A new study⁴ has been designed to test the use of focused ultrasound ablation, low-dose gemcitabine (a chemotherapy) and the combination of focused ultrasound ablation plus low-dose gemcitabine in patients with early-stage breast cancers. They will be testing the effects of each of these regimens on cells in the immune system. They hypothesize that the combination of focused ultrasound ablation and gemcitabine will decrease myeloid-derived suppressor cells and will increase T cell activity. They also hypothesize that focused ultrasound ablation and low-dose gemcitabine will be safe and will result in non-inferior surgical completion rates and tumor margin assessments. “The cooperation established with the University of Virginia in their investigations should benefit breast cancer patients and pave the way for a new era of treatment offering an alternative to surgery” said David Caumartin, CEO of Theraclion.

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About University of Virginia Cancer Center

The UVA Cancer Center is one of 71 centers in the US with designation from the National Cancer Institute. US News & World Report has ranked the UVA Medical Center as the No. 1 hospital in Virginia and its cancer services among the top 10% in the United States. It is designated as a Center of Excellence by the Focused Ultrasound Foundation and is home to the first fully dedicated focused ultrasound facility in the world. The center is renowned for its research and development strategy and for its innovative clinical trials.

About Theraclion

Theraclion has developed an innovative echotherapy solution using High Intensity Focused Ultrasound for the treatment of varicose veins, SONOVEIN®. The treatment solution, which obtained CE marking in April 2019, is based on the leading-edge echotherapy treatment expertise developed by Theraclion over years for non-invasive ablation of breast fibroadenomas and thyroid nodules using its ECHOPULSE® solution. Further improvements to the ECHOPULSE technology are the foundation for SONOVEIN to provide the only non-invasive ablation therapy for varicose veins. This procedure allows for treatment without a catheter, chemical injection, or incision. An operating room is not necessary, and the treatment can be performed at a doctor’s

⁴ Focused Ultrasound with Low-Dose Gemcitabine to Augment Immune Control of Early-Stage Breast Focused Ultrasound and Gemcitabine in Breast Cancer - Full Text View - ClinicalTrials.gov



offices or in clinics, as well as in hospitals. Venous pathology is widespread worldwide and generates around 5 million treatment procedures per year, according to Millennium research Varicose Vein Device Market Study 2015. Theraclion's technological solutions are based on high-tech ultrasound medical devices that are precise and easy to use for practitioners.

Located in Malakoff, near Paris, Theraclion brings together a team of 25 people, more than half of whom are dedicated to R&D and clinical trials.

For more information, please visit the Theraclion website: www.theraclion.com and the patient site: <https://echotherapie.com/echotherapy/>

Theraclion is listed on Euronext Growth Paris
Eligible for the PEA-PME scheme
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