



## **Theraclion Announces FDA Authorization to Start U.S. Trial for Immunotherapy and Echotherapy Combination on Breast Cancer**

**Study led by University of Virginia aims to extend the benefits of immunotherapy in cases of metastatic breast cancer via the combined effects of echotherapy and pembrolizumab**

**Malakoff - FRANCE, June 26, 2017 - THERACLION** (Alternext, FR0010120402 - ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced its long-term academic partner, University of Virginia (UVA), has received authorization from the U.S. Food and Drug Administration (FDA) to proceed with a new clinical study to evaluate the potential of treatment combining echotherapy (also known as High Intensity Focused Ultrasound, HIFU) with pembrolizumab, a modern immunotherapy drug targeting PD-1 checkpoint Inhibitor.

Immunotherapy stimulates the body's own immune system to fight tumor cells. HIFU, which has already demonstrated its efficacy in the treatment of malignant and benign tumors, could have a major impact on the efficacy of immunotherapy when delivered as a combined treatment as it may locally potentiate the immune response induced by these drugs.

*"Immunotherapy treatments help the body to fight against cancerous cells. This new treatment method is expected to have fewer side effects than existing cancer treatment alternatives. Nevertheless, large, solid masses are difficult for the immune system to access,"* explained Patrick Dillon, M.D., Associate Professor of Hematology and Oncology at the University of Virginia, Charlottesville, USA.

*"The HIFU treatment could be used to pre-treat a tumor in order to shrink the overall volume and, perhaps more importantly, allow the patient's own immune system to access and recognize the malignant cells,"* added David Brenin, M.D., Chief of Breast Surgery, co-director of the University of Virginia Breast Care Program, Associate Professor of Surgery at UVA's School of Medicine.

UVA is a pioneer in immunotherapy research. It has developed the Immunology/Immunotherapy program (IMM) featuring outstanding basic science research and highly collaborative, translational initiatives to develop clinical trials based on this research. The program is led by internationally recognized physicians in the field of cancer immunotherapy. UVA has been equipped with Theraclion's echotherapy system Echopulse® since 2014. The Echopulse is being evaluated in a feasibility study in the US for non-invasive treatment of breast fibroadenomas.

Although immunotherapy drugs have gained widespread adoption and demonstrated spectacular results in a number of indications, none have yet demonstrated better outcomes for women with stage IV metastatic breast cancer. Breast cancer is the most commonly diagnosed cancer among women worldwide. Each year, breast cancer accounts for 12 percent of all cancers diagnosed globally, and it is the second leading cause of cancer-related death among women. In 2012, there were approximately 1.68 million new diagnoses worldwide and 520,000 deaths. Approximately 1 in 8 U.S. women will develop



invasive breast cancer at some point in their lives; for men, the lifetime risk is about 1 in 1,000<sup>1</sup>. Despite newly developed screening methods, better awareness, and advanced therapeutic treatments, still up to 30 percent of women diagnosed with early-stage breast cancer will eventually develop metastatic breast cancer<sup>2</sup> with a poor prognosis.

*“To our knowledge, this will be the first study combining HIFU and immunotherapy drugs in the field of breast cancer. Our system is specifically adapted for this combination treatment, as it is the only robotic system with flexible access to the target. We are eager to see this kind of investigation, as we have always committed to our customers and shareholders that we will leverage our outstanding clinical results in benign tumors into progress treating malignant disease,”* says David Caumartin, CEO of Theraclion. *“This is a critical milestone for today’s breast users, gynecologists, oncologists and radiologists, who are excited to explore this new path in the fight against cancer.”*

#### **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](http://www.theraclion.com).

**Theraclion is listed on Alternext Paris**

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<sup>1</sup> <http://www.cancerresearch.org/cancer-immunotherapy/impacting-all-cancers/breast-cancer#sthash.vjeVGGNS.dpuf>

<sup>2</sup> <http://www.breastcancer-matters.eu/metastatic-breast-cancer-other-half-story?gclid=CKmijuzbsNQCFbYV0wodBIEIMQ>