Echotherapy specialist Theraclion performed its first two non-invasive treatments of benign breast tumors in the U.S.

The feasibility study is the first step toward obtaining the marketing approval for the Echopulse in the United States

Paris, May 20th, 2014 – Theraclion (Alternext, FR0010120402 - ALTHE, PEA PME-eligible), a company specialized in advanced medical equipment for echotherapy, announces the realization of the first treatments of breast fibroadenoma with the Echopulse® device in the United States. Last February the U.S. Food and Drug Administration granted the company an IDE (Investigational Device Exemption), allowing it to conduct this clinical trial, which is the first step toward obtaining the PMA (Premarket approval) in the United States.

Jointly conducted with the University of Virginia, U.S., the study aims to collect data on the safety and efficacy of the Echopulse® for the indication of breast fibroadenoma. The Echopulse® is a high-tech device, combining ultrasound imaging and therapeutic intervention through high-intensity focused ultrasound (HIFU).

Performed on two American female patients, the treatment was carried out jointly by doctors David Brenin and Carrie Rochman in the outpatient unit of the university radiology department. Both procedures were performed in less than an hour, with the patients under conscious sedation.

"The treatment of the first two patients participating in this clinical trial in the United States went very well. The Echopulse® device is easy to use, and the patients responded well to the treatment. The two patients were able to return home shortly after the procedure," declared Dr. Brenin, associate professor of surgery at the University of Virginia, U.S.

The feasibility study will enroll altogether 20 patients suffering from breast fibroadenoma. Following the procedure, the patients will be monitored for a six-month period in order to measure the progressive size reduction of the tumors as well as the rate of the symptoms disappearance. This first study will be followed by a pivotal multicenter study, whose outcomes will be the main deciding factor in the Food and Drug Administration marketing approval of the Echopulse® in the United States.

Benign breast tumors constitute a growing percentage of detected breast pathologies and we estimate that 10% of women will develop a fibroadenoma in their lifetime. A market survey of the diagnosis and therapy of breast tumors (performed by Life Science Intelligence in 2007) showed that over 1,300,000 million cases of breast fibroadenoma were diagnosed in 2006. More than 50% of them needed

therapeutic excision. The same survey estimated that 1,490,000 million cases of breast fibroadenoma would be diagnosed in 2012.

The Echopulse® opens up a new era in the treatment of breast fibroadenoma without significant side effects for the patient. The removal is scarless and non-invasive. The absence of postoperative infection is ensured by the absence of skin damage. This outpatient procedure is performed under local anesthesia or conscious sedation, enabling patients to immediately resume their normal activities. The flexibility of the process and the absence of hospitalization can reduce costs and optimize care management.

The Echopulse® technology is already marketed in the European Union and has been awarded the CE label for the treatment of breast fibroadenoma and benign thyroid nodules. It is thus entitled to an upcoming marketing in the Middle East, Africa and some countries in Asia and Latin America.

"We are delighted by the excellent launch of this study. In Europe, more than a hundred treatments of breast fibroadenoma with the Echopulse® have already been successfully performed. This first clinical study in the United States is a key step toward commercializing the Echopulse® in the North American market," explained Stefano Vagliani, CEO of Theraclion.

About Theraclion

Based in Paris, Theraclion is an echotherapy specialist and leader in non-invasive treatment of benign tumours with high-intensity focused ultrasound (HIFU) guided by real-time ultrasound imaging. The company has developed a medical device (Echopulse®) that combines advanced ultrasound imaging and HIFU therapy. Theraclion is ISO 13485 certified and has received the CE mark for non-invasive ablation of breast fibroadenomas and thyroid nodules. A full 70% of its 19-strong team are dedicated to R&D and clinical trials. For more information visit www.theraclion.com

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