



Theraclion receives CE marking approval for its ultrasonic device EchoPulse, in the non-invasive treatment of breast fibroadenomas

- ✓ *Fibroadenoma is the most widely spread breast benign tumor ;*
- ✓ *EchoPulse has already been validated in European clinical trials.*

Paris, 12 December 2012 - Theraclion, a specialist in state-of-the-art medical technology dedicated to echotherapy that uses ultrasound-guided High Intensity Focused Ultrasound (HIFU) has received the CE marking approval for the non-invasive treatment of breast fibroadenomas, a first in this indication. This treatment will benefit thousands of women.

"The CE marking widens the use of our technology in the major area of breast fibroadenoma. Our technology can now be offered to all women suffering from this pathology in Europe. They can benefit from a non-invasive outpatient treatment without general anesthesia which puts an end to the embarrassment and anxiety triggered by this kind of tumor. Non-invasive focused ultrasound surgery guided by real-time ultrasound imaging is consistent with the logic of developing lesser invasive treatments and a reduction of health costs. This market authorization in Europe will allow us to grow by creating non-invasive surgery centers based on our resulting echotherapy solution within leading hospitals and clinics. Other tumors beside breast fibroadenomas will be treated in a non-invasive manner in the near future" says Jean-Yves Burel, CEO of Theraclion.

Echotherapy is a new non-invasive therapeutic approach with ultrasound-guided focused ultrasound, in which high intensity focused ultrasounds (10,000 times higher than normal ones) are used for a specifically localized ablation with no skin damage. The ultrasounds are focused on a small area where the temperature rise leads to tissue necrosis. This treatment precision avoids harming healthy tissues around the lesion. The echotherapy is a technique that enables practitioners to visualize and treat simultaneously a tumor such as fibroadenoma with no incision or scar.

Fibroadenoma is the most widely spread breast benign tumor as 10% of women risk developing it in their lifetime. It represents more than half of breast biopsies. This pathology hits women of all ages but is a lot more frequent with women under 30. Estimates show that 50,000 fibroadenoma tumors are diagnosed each year in France, with 320,000 in Europe and 640,000 in the U.S.

"I used the EchoPulse to treat 11 patients during a clinical trial at the American Hospital of Paris from January to October 2012. The results from this technique are encouraging with a 60% volume reduction of fibroadenoma in an average period of 6 months. EchoPulse could represent an interesting alternative to classical surgery" adds Dr Marc Abehsera from the medical imaging service at the American Hospital of Paris.

"It is interesting participateto the assessment of echotherapy in breast fibroadenoma in the French trial. We are hoping to participate in a multicenter trial that will measure the effects of this type of treatment in breast cancer", says Dr Edouard Poncelet from the woman imaging service at the Valenciennes Hospital Centre (Centre Hospitalier de Valenciennes).

A clinical trial on 40 patients has shown the efficiency and the excellent tolerance of echotherapy for this type of pathology. To this day, 48 fibroadenomas have been treated in 3 French centers (Lille Jeanne de Flandres Hospital, the Valenciennes Hospital and the American Hospital of Paris) and one center in Bulgaria (the University Hospital of Sofia), with significant volume reductions accompanied by the resolution of symptoms.

About EchoPulse

EchoPulse, the medical device developed by Theraclion uses HIFU (High Intensity Focused Ultrasounds). EchoPulse uses ultrasound imaging as a targeting system and high intensity focused ultrasounds for tissue necrosis, thus preventing patients to undergo a surgical procedure. EchoPulse is unique as it combines in the same device an imaging monitoring and treatment system while remaining compact and mobile. In addition to its ergonomic advantage, it offers excellent quality of image, a millimetric accuracy of wave shots and an integrated cooling system for the patient's safety. The advantages offered by EchoPulse are beneficial for the patients (non-invasive, scarless and mobile treatment, conscious sedation) but also for the practitioners (fast, efficient and harmless) and hospital centers (efficient, lesser costs of hospitalization, one device for several pathologies). The reimbursement of costs of the proceedings is currently under consideration.

About Theraclion

Theraclion is the Paris-based ultrasound therapy specialist and leader in non-invasive treatment of superficial lesions with High Intensity Focused Ultrasounds (HIFU) monitored by real-time ultrasound imaging. The company has developed the EchoPulse technology platform that combines ultrasound imaging with high intensity focused ultrasound therapy. After 20 years of cutting-edge research and development, this non-invasive "surgery" enables the very accurate destruction of small areas of tissue delimited by the physician. Theraclion targets two clinical indications; neck glands and breast fibroadenomas and will announce new ones in the following months. Theraclion is financed by the investment fund Truffle Capital, public funds and OSEO. For more information on Theraclion, visit <http://www.theraclion.com/>

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