Theraclion obtains FDA approval for the USA's first clinical trial of echotherapy in the treatment of breast fibroadenoma

This feasibility study constitutes the first step towards marketing approval in the USA

Paris, April 3, 2014 - Theraclion, a company specialized in advanced medical equipment for echotherapy, today announced that the American Food and Drug Agency granted it an Investigational Device Exemption (IDE) on February 6 this year. The IDE constitutes authorization to proceed with a feasibility study to evaluate the treatment of breast fibroadenoma with the Echopulse® device.

In collaboration with the University of Virginia, the study will be conducted on 20 patients with breast fibroadenoma and is designed to collect data on the safety and efficacy of the Echopulse® in this indication. The Echopulse® is a high-tech device utilizing high-intensity focused ultrasound (HIFU) treatment guided by ultrasound imaging. The trial is the first phase of the product marketing application in the USA and will be followed by a pivotal multicenter study.

Benign breast tumors constitute a growing percentage of detected breast pathologies. the estimation is 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 1.3 million cases of breast fibroadenoma were diagnosed in 2006. More than 50% of these needed therapeutic excision. The same survey estimated that ~1.5 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 scar-free and non-invasive. The absence of skin damage reduces the likelihood of postoperative infection. 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. Theraclion intends to market the device in the Middle East, Africa, Asia and Latin America. Registration in China and in the USA are expected respectively by the end of 2015 and 2017.

"We are delighted with this approval from the FDA, which marks the first step in the clinical trial and marketing application process for Echopulse® in the United States", commented Theraclion's CEO Stefano Vagliani.

About echotherapy

Echotherapy is a new non-invasive therapeutic approach that involves the use of high-intensity focused ultrasound (HIFU) to produce very localized ablation without skin damage. The ultrasound is focused on a previously defined zone within which the increase in temperature causes necrosis of the targeted tissues. This avoids damage to the healthy tissue around the lesion. Echotherapy enables tumors (such as thyroid nodules and breast fibroadenoma) to be simultaneously viewed and treated, without incision or scarring.

About Theraclion

Located in Paris, Theraclion is an echotherapy specialist and a leader in non-invasive treatment of benign tumors with high-intensity focused ultrasound (HIFU) guided by real-time echography. The company has developed a medical device (Echopulse®) that combines ultrasound imaging and HIFU therapy. Theraclion is ISO 13485 certified and received the CE mark for non-invasive ablation of breast fibroadenomas and thyroid nodules. Theraclion has a team of 19 people, of which 70% fully devoted to R&D and clinical trials. Theraclion's main investor is Truffle Capital (a leading European venture capital firm) and also receives research funding from Bpifrance (formerly OSEO, the French state innovation agency).

For more information, visit http://www.theraclion.com

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