Theraclion Announces First Patients Treated in U.S. pivotal multicentre FDA Study

Malakoff, FRANCE – February 8th, 2017 – Theraclion (Alternext, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced that the first patients were treated in the U.S. pivotal clinical trial to evaluate the safety and efficacy of Echopulse® echotherapy as a non-invasive treatment of breast fibroadenomas (BFAs).

The prospective clinical trial will enroll approximately 100 patients at four centers in the U.S., University of Virginia School of Medicine, NYU Langone Bellevue, Montefiore Medical Center (NY) and New York-Presbyterian/Columbia University Medical Center and one in Europe with Tübingen University Hospital, Germany. Patients will receive a single high-intensity ultrasound treatment with Echopulse®. The primary endpoint is a reduction of fibroadenoma volume, pain and anxiety. The first two cases were treated at the UVA site on January 20th, 2017.

"High intensity focused ultrasound (HIFU) technology is exciting because it has the potential to provide patients with an alternative to surgery, avoiding a scar, with minimal interruption in their normal daily activity," said 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, and Principal Investigator of the Echopulse® U.S. trial.

David Caumartin, CEO of Theraclion concluded, *"The U.S. market for non-invasive treatment alternatives for BFA is significant. There are approximately 400 thousand surgeries to remove BFAs in the U.S. each year. We believe that patients are searching for alternatives to invasive surgery that are outpatient, of short duration, generate minimal or no post-treatment pain and no scarring. This clinical trial is a significant step toward bringing our Echopulse® echotherapy to U.S. patients."*

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.

Theraclion is listed on Alternext Paris
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