



French authorities grant derogation reimbursement for Theraclion's medical device Echopulse®

Malakoff, FRANCE – December 15, 2016 – Theraclion (Alternext, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced that the French's National Health Authority (HAS) has issued a favorable opinion on the exceptional reimbursement (*Forfait Innovation*) of its medical device, Echopulse®, for the treatment of breast fibroadenomas.

On February 16th, 2015, the French Ministry of Health has issued a decree introducing a new derogatory reimbursement process for innovative health technologies, process called *Forfait Innovation*. The two main objectives of this new system are to accelerate patient access to medical innovations and to support the development of companies that are behind them. According to Prof. Jacques Belghiti, President of the National committee for the evaluation of medical devices and health technologies (CNEDiMETS), *"This new process allows for fast-track medical innovation into the system whilst collecting complementary data at the same time. Theraclion has been the first company to submit for the new Forfait Innovation¹ and is the first company to be granted it."*

Theraclion submitted a dossier for its Echopulse® system. *"The clinical studies we have already done have demonstrated patient safety and the clinical effectiveness of our system. The Forfait Innovation will make it possible to go further, comparing safety and efficacy of echotherapy with Echopluse® to the current reference procedure, surgery, with particular emphasis on measuring less pain and relieving anxiety for patients,"* explains Dr. Michel Nuta, MD, Chief Medical Officer of Theraclion.

Anja Kleber, VP Marketing and Market Access of Theraclion, adds: *"We opted for a health-economic study with the aim to determine economic advantages of echotherapy for breast fibroadenomas compared to surgery. The use of our system does not require a sterile environment such as a surgical suite, an anesthesiologist, a wake-up room or even a hospital bed. There are no post-operative wound care activities related to the procedure as it is 100% non-invasive."*

Twelve highly reputed centers from all over France, both from the private and the public sector, will participate in the study. All treatments performed by these centers will be covered by the national insurance system during the 30 months of patient recruitment, follow-up and beyond, at a level comparable to the rate established for surgery. This continues until the analysis of the study data has been conducted and enabling regulators to make a decision on permanent reimbursement of echotherapy for breast fibroadenomas.

"We are eager to start this study as soon as possible", says Prof. Richard Villet, Member of the National Academy of Medicine, former President of the French Society of Senology. *"It has not only the support of the future users in France but has also been supported by the French professionals' national council for Gynecology and Obstetrics (CNPGO). For all of us, this first step of patient access to the technology opens*

¹ Since the introduction of "Forfait Innovation" in 2009, two pilot projects have been launched. The 2015 reform clarified the process required to ultimately receive coverage.



up research possibilities in malignant disease by getting this technology into the hands of those who manage these diseases."

"The crucial step we have just taken, reimbursement in our home country, is of strategic importance for Theraclion and for all the innovative French companies that could accelerate their development thanks to a more established national market. Beyond France, the Forfait Innovation will be of great value to us. It meets the highest evaluation criteria with the realization of a randomized study and demonstrates the confidence that the public authorities give to our technology and to our company," concludes David Caumartin, CEO of Theraclion.

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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