



Theraclion's Echopulse® Covered by French National Health Insurance for the Treatment of Breast Fibroadenomas

The treatment of breast fibroadenomas with high intensity focused ultrasound (HIFU) is covered within the *Forfait Innovation* process

Malakoff - FRANCE, July 12, 2017 - THERACLION (Alternext, FR0010120402 - ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced the publication in the Official Gazette of the order relating to the reimbursement for its medical device Echopulse® for the treatment of breast adenofibromas, pursuant to Article L. 165-1-1 of the Code of Social Security: <https://www.legifrance.gouv.fr/eli/arrete/2017/6/28/SSAH1719144A/jo/texte>

This flat-rate coverage is for a period of four years, including one year of inclusion period, one and a half years of follow-up, six months of data analysis and one year of re-evaluation processes by the French's National Health Authority (HAS). It will be effective in a multicenter, randomized study comparing treatment with Echopulse® to reference treatment by surgery. The amount of the package includes patient care and the associated hospitalization expenses and is thus set per patient at 1,300 €. In case a sufficient expected benefit is obtained at the end of the study, the Economic Committee for Health Products or, as the case may be, the health insurance, will fix a final pricing for breast fibroadenoma treatment with echotherapy.

Twelve highly reputed centers from all over France, both from the private and the public sector, will participate in the study: Groupe Hospitalier Diaconesses Croix Saint-Simon (Paris), CHU Strasbourg, Hôpital Tenon (Paris), Hôpital Saint Louis (Paris), Hôpital Pitié-Salpêtrière (Paris), Hôpital Européen (Marseille), Centre Hospitalier Valenciennes, CHU Montpellier, Clinique Mutualiste La Sagesse (Rennes), Polyclinique de l'Atlantique (Saint Herblain), American Hospital of Paris (Neuilly-sur-Seine), Polyclinique Majorelle (Nancy). All treatments performed in these centers will be reimbursed by the French Health Insurance. Thus, six hundred patients, among which 150 within the study, will be eligible for this coverage.

"Obtaining the Forfait Innovation is great news for Theraclion and for the entire healthcare ecosystem in France. First of all, it was the culmination of an extremely demanding selection procedure that allowed Theraclion to establish a relationship of trust with the Ministry of Health and the French National Health Authority. French reimbursement of echotherapy will be a major factor in accelerating the development of Theraclion and encouraging it to continue on the path of innovation. It is worth noting that Theraclion is the first French company to obtain the Forfait Innovation in its revised form, paving the way for other French Medtech companies who are ready to embark on the national market," explains David Caumartin, CEO of Theraclion.

About Forfait Innovation

On February 16th, 2015, the French Ministry of Health has issued a decree introducing a new derogatory reimbursement process for innovative health technologies, 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.



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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