



## Theraclion Extends Market Access and Regulatory Approval

- NICE (UK) published guidance for the use of Echopulse® in fibroadenoma
  - Echopulse® achieved regulatory approval in Russia

**Malakoff, FRANCE – September 27, 2017 – THERACLION** (Alternext, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced that the British National Institute for Health and Clinical Excellence (NICE) has published guidance within the framework of its interventional procedure program for high-intensity focused ultrasound for symptomatic breast fibroadenoma. Theraclion also announced obtaining regulatory approval from the Russian Ministry of Health.

### **Important Market Access Milestone for Echopulse®: NICE published IPP guidance for Echotherapy**

Theraclion's echotherapy procedure using high-intensity focused ultrasound is now listed on NICE's website with guidance of its interventional procedures program (IPP) for the non-invasive treatment of breast fibroadenoma. The guidance announces that "the evidence on high-intensity focused ultrasound for symptomatic breast fibroadenoma raises no major safety concerns" and NICE recommends that patients should be treated "with special arrangements" for clinical governance, patient consent and audit or research. The IPP includes a literature review, physician input and patient input. One patient commented: *"HIFU was for me the only acceptable therapy for treating my benign tumor as it is the only non-invasive alternative to surgery without scars, without anesthesia, without hospitalization and with immediate recovery. It is much more satisfactory than having surgery and I hope HIFU will keep on developing and become much more renowned. From my patient's point of view, HIFU should become the standard of care for fibroadenoma."*

NICE is an independent organisation responsible for providing national guidance to the UK on the promotion of good health and the prevention and treatment of ill health. *"Having echotherapy recognized by NICE is not only of great importance for UK & British Commonwealth markets but also across the world. Indeed, NICE is often used as a reference for many other healthcare systems (healthcare insurances/ authorities) in Northern Europe as well as in India, Australia, Canada, Korea, and Hong-Kong."* explains Mike Leach VP UK, Northern Europe and MEA of Theraclion.

## Regulatory approval in Russia

The Russian Ministry of Health has granted regulatory approval for the Echopulse system. According to various sources, between 15 and 40% of Russia's population suffer from thyroid pathologies. In some regions, the percentage of patients requiring thyroid treatment could even be close to 95%.<sup>1</sup> Such a high incidence rate is due to three leading factors: firstly, social factors, leading to a deterioration in nutrition and the reduction of intake of iodine-containing products by large segments of the population. The WHO recommends a daily 150mcg iodine intake whereas the Russian average iodine intake is as low as 40-80mcg/day<sup>2</sup>; secondly, the destruction of the state system for the prevention of goitres and iodine deficiency; and finally, the exposure to radiation caused by the 1986 Tchernobyl accident.

*"We are very happy to have obtained the regulatory approval in Russia after a 3-year process. This approval not only creates opportunities in Russia but also in neighbouring countries such as Belarus, Kazakhstan, Tajikistan, Uzbekistan and Kyrgyzstan, all together counting around 200 million inhabitants."* concluded 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](http://www.theraclion.com)

**Theraclion is listed on Alternext Paris**

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**Mnemonic: ALTHE - ISIN Code: FR0010120402**



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<sup>1</sup> <http://wellew.ru> – Russian portal dedicated to thyroid health

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