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Theraclion announces study in non-invasive varicose vein treatment and the launch of a capital increase through a private placement

- **The ongoing clinical trial investigates the Echopulse® device for the treatment of insufficient superficial and perforating veins of the lower limb (varicose veins)**
- **Theraclion launches a capital increase through private placement with institutional investors for a minimum amount of approximately 3 million euros to fund the clinical trials**
- **In parallel, the funds managed by Truffle Capital will sell at least 177,726 Theraclion shares for the benefit of qualified investors by way of block sale and lock-up commitment for 12 months**

Malakoff, France – October 16, 2017 – THERACLION (Euronext Growth, FR0010120402 – ALTHE), a company specialized in leading-edge medical equipment for echotherapy, today announced that a clinical trial is currently investigating the use of its Echopulse® device to treat insufficient superficial and perforating veins of the lower limb (varicose veins) with non-invasive High Intensity Focused Ultrasound (HIFU), also called echotherapy. To fund the trials and other on-going strategic developments, Theraclion announces today the launch of a capital increase with cancellation of preferential subscription rights, in favor of qualified investors through a private placement for a minimum total proceed of approximately 3 million euros.

The ongoing clinical trial investigates the Echopulse® device for the treatment of insufficient superficial and perforating veins of the lower limb (varicose veins)

Dr. Alfred Obermayer from Austria, a surgeon specialized in venous treatments and principal investigator of the study, is currently recruiting subjects. Dr. Obermayer benefits from a significant experience with minimal invasive treatment methods, such as radiofrequency ablation and laser treatments. *“Echotherapy HIFU treatments could offer to patients a completely non-invasive approach to treat varicose veins”* says Dr. Obermayer.

In two months only, 25% of the cases planned in the study were treated with promising acute results and lack of significant adverse events.

The trial, *“Minimally Invasive Treatment of Insufficient Superficial and Perforating Veins of the Lower Limb using HIFU: A single Center Prospective Study - Archimedes 01,”* has the primary objective to determine the efficacy, safety, tolerability and surgeon ease of use of the Echopulse® system for extra corporeal HIFU delivery in targeted tissues.

Further details are posted on www.clinicaltrials.gov (identifier NCT03304834).

“The goal of this trial is to explore the safety, efficacy and feasibility of our technology, in terms of reflux abolition,” remarked Michel Nuta M.D., CMO of Theraclion. *“Our hope is to offer a non-invasive new option for the growing number of patients suffering from chronic veins disease (CVD). Many of these patients, especially in recurrent disease or presence of active ulcer, do not respond well to existing surgical or endovenous treatments.”*

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In the adult Western population, the prevalence of varicose veins is 20% of the population (range, 21.8%-29.4%), and about 5% (range, 3.6%-8.6%) have venous edema, skin changes or venous ulcerations. Active venous ulcers are present in up to 0.5%, and between 0.6% and 1.4% have healed ulcers.¹ On the basis of estimates of the San Diego epidemiologic study, more than 11 million men and 22 million women between the ages of 40 and 80 years in the United States have varicose veins, and 2 million adults have advanced CVD, with skin changes or ulcers.¹ The Bonn Vein Study², which enrolled 3072 randomly selected participants (1722 women and 1350 men), aged from 18 to 79 years, found symptoms of CVD in 49.1% of men and in 62.1% of women. A French cross-sectional survey found varicose veins in 23.7% of men and 46.3% of women.³

Launch of a capital increase

Theraclion announces the launch of a capital increase with cancellation of preferential subscription rights, in favor of qualified investors through a private placement for a minimum total proceed of approximately 3 million euros.

The net proceeds of this private placement will enable Theraclion to:

- accelerate its commercial deployment in Germany and Hong Kong,
- build its deployment in China,
- investigate the Echopulse[®] device for the treatment of insufficient superficial and perforating veins of the lower limb (varicose veins),
- continue the pivotal trial underway to obtain access to the United States market in the indication of fibroadenoma,
- perform the first clinical trial in the world combining echotherapy and immunotherapy, in the treatment of metastatic breast cancer in accordance with legal and regulatory provisions.

This capital increase will be carried out pursuant to the 11th resolution of the Ordinary and Extraordinary Shareholders' Meeting of May 11, 2017 and in accordance with Article L. 411-2 II of the French Monetary and Financial Code, through a private placement, in favor of institutional investors in France and outside France.

The private placement will be conducted by way of an accelerated book-build process, beginning immediately and expected to close prior to market opening tomorrow, subject to early termination or extension. The capital increase through the accelerated book-building is open to institutional investors in France, in any Member State of the European Economic Area in accordance with the exemptions of Article 3(2) of the European Directive 2003/71/EC of the European Parliament and European Council (as amended) to the extent they have been transposed by the relevant Member State or, otherwise, in cases not requiring the publication of a prospectus under aforementioned Article 3(2) and/or the applicable regulations in such Member State, and elsewhere outside the United States of America in reliance on Regulation S under the U.S. Securities Act of 1933 (the "**Securities Act**"). Simultaneously, the Company is undertaking a private placement in the United States to "qualified institutional buyers" as defined in Rule 144A under the Securities Act or to "institutional 'accredited investors'" as defined in Rule 501(a) thereunder.

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The Company will announce the results and final terms of the private placement on October 17, 2017 (before opening of markets) in a press release. The settlement and delivery of the new shares is scheduled for October 19, 2017 on the Euronext Growth market.

The issue price of the new shares shall be at least equal to the weighted average price of the Theraclion share on the Euronext Growth Paris market for the last 20 trading days preceding the fixing of the issue price, which may be reduced up to a maximum of 20%, with a limit of 20% of the share capital, ie a maximum of 1,298,523 new shares to be issued. The new shares will be the subject of an application for admission to the Euronext Growth market from Euronext.

The private placement will be led by Invest Securities acting as global coordinator and bookrunner. It will not require a prospectus subject to the approval of the *Autorité des marchés financiers*.

This press release does not constitute an offer to subscribe and the offer of the new ordinary shares does not constitute an offer to the public in any jurisdiction.

In connection with the private placement, an undertaking to abstain from issuing or disposing of any shares of the Company at a price lower than that of the capital increase, for a period of 90 days from the date of settlement delivery, has been granted by Theraclion to the global coordinator and bookrunner.

Partial block sale of shares held by the funds managed by Truffle Capital

In parallel with the private placement, the funds managed by Truffle Capital will sell at least 177,726 Theraclion shares, ie 2.74% of the share capital, for the benefit of qualified investors by way of block sale at the price of the order book. Subject to the completion of such sale, Truffle will refrain from selling any shares of the Company, except by way of block trades with the prior written approval from Invest Securities, for a period of 12 months from the date of the transaction.

About the Clinical Trial of the Echopulse® device

The subjects in this trial are patients who have been diagnosed with CVD and are presenting with venous reflux associated with lower limb superficial venous network insufficiency, recurrence at the thigh/groin level or perforator incompetence.

This is designed as a single center, prospective, single arm, open-label trial involving 35 subjects. The trial includes a single HIFU treatment session and 3 months of follow-up.

Subjects will undergo Duplex ultrasound examinations before and at each post procedural follow-up visit.

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

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together a team of 35 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 Euronext Growth Paris
PEA-PME eligible
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