



## **A break-through for medical cooling of stroke patients**

BrainCool AB (publ) would like to share and distribute the information set out in the press release below from EUROHYP-1, a phase III clinical trial of medical cooling of stroke patients.

The clinical study of the first 62 patients confirms therapeutic cooling to be a safe and well tolerated treatment for stroke. The result enables the EUROHYP-1 to continue the research to evaluate the effectiveness of cooling.

By extending the study to more than 30 additional trial sites at hospitals located in 16 countries, it will accelerate the enrollment of patients in order to complete the study of 800 patients within three years. Furthermore the clinical protocol has been adapted to facilitate the inclusion of patients. One new product, The BrainCool System that monitors shivering, is integrated into the clinical trial and it will be offered in several countries.

The effectiveness of cooling might be demonstrated with as few patients as 250. The researchers are also paying close attention to automated detection of shivering.

- BrainCool is well positioned to take advantage of the findings of the EUROHYP-1 study and to enter in the clinical trial to support in further inclusion of patients, says Martin Waleij, CEO of BrainCool.

For further information

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## **New revolutionary stroke treatment – safety and tolerability of therapeutic cooling confirmed in a pan-European clinical trial**

***Brussels, October 7, 2016 - Cooling the brain within 6 hours of a stroke appears safe and well tolerated in a pan-European trial funded by the European Commission. If the expected efficacy is confirmed, this procedure can be rolled out across Europe with the potential of benefiting tens of thousands of patients each year.***

Stroke is the largest killer after ischemic heart disease in Europe and yet, there are limited number of treatments available. Thanks to the progress achieved with EUROHYP-1, a phase III clinical trial led by Universitätsklinikum Erlangen, funded by the European Commission under the Seventh Framework Programme, therapeutic hypothermia appears to be a safe and well tolerated treatment. *“That the treatment appears safe and well tolerated is exciting news for patients and allows us to continue our research to evaluate the effectiveness of therapeutic cooling”* said **Malcolm Macleod**, Professor of Neurology and Translational Neurosciences at the University of Edinburgh, United Kingdom, and one of the Principal Investigators in the trial.

Therapeutic hypothermia, or cooling, is already used effectively in reducing ischemic brain injury following cardiac arrest and birth injuries. It probably acts by inducing a kind of hibernation in the brain, minimizing the need for oxygen and preventing further damage.

The safety and tolerability of therapeutic cooling has been studied in preliminary findings from the first 62 patients enrolled into the EuroHYP-1 clinical study in Belgium, Denmark, France, Germany, Spain and U.K. The patients enrolled into the EuroHYP-1 trial rated their experience as “positive” and the large majority of them (72%) were likely or very likely to recommend the therapeutic cooling to others.

The researchers in EuroHYP-1 are paying close attention to the results of the tolerability surveys to identify further improvement opportunities in the delivery of therapeutic cooling: introduction of a new cooling technology with an even better tolerability profile thanks to an automated detection of shivering is one of these measures which is tested currently.

*“In the coming 6 months the EuroHYP-1 consortium is preparing to start enrolling patients in more than 30 additional trial sites at hospitals located in 16 countries, including Austria, Czech Republic, Finland, Ireland, Italy, Lithuania, Poland, Sweden and Turkey.”* said Dr. Macleod, *“Thanks to these additional country and site openings we expect an acceleration of the enrolment of patients into the clinical trial, enabling us to target to complete the study within 3 years. It is important to mention that the efficacy of therapeutic cooling might be demonstrated with as few as 250 patients if the health improvement delivered is equal to the treatment results achieved with thrombectomy, a highly effective treatment from which, unfortunately, few patients are currently able to benefit. However, to make sure we detect any significant health improvement resulting from therapeutic cooling, the objective is to recruit up to 800 patients in total”*.

EuroHYP (the European Stroke Research Network for Hypothermia), in collaboration with the clinical trial units of universities, including Erlangen, Edinburgh, Copenhagen, Malmö, Utrecht, Lille and Glasgow, has become the driving force behind an international consortium that has brought together the expertise and synergies essential for this large scale trial.

*“Right now the primary focus of our research consortium is to recruit in a fairly short time an additional 730 patients with acute ischemic stroke to ascertain the treatment benefits of therapeutic cooling”* said **Prof. Dr. Stefan Schwab**, Professor and Chair of the Department of Neurology at the Friedrich-Alexander-University Erlangen-Nürnberg, Germany, who has been at the forefront of many hypothermia stroke trials conducted in the past and now leads the Consortium.

The confirmation of safety and tolerability in the EuroHYP-1 trial is a key milestone for the study of therapeutic cooling and in case efficacy is also proven, it is anticipated to contribute to the transformation of acute stroke care world-wide, comparable to the introduction of intravenous thrombolysis in 1995.

*“The safety and tolerability of therapeutic cooling is especially remarkable in light of the numerous failures seen with experimental drugs”* said **Dr. Bernd Kallmünzer**, from the Department of Neurology at the Friedrich-Alexander-University Erlangen-Nürnberg, Germany, *“based on a review of stroke studies conducted since 1950, researchers found that out of 85 promising drugs only two were found beneficial: aspirin and the clot-buster known as tissue plasminogen activator. We hope that through EuroHYP-1, a pan-European research funded by the European Commission, within a few years we will be able to identify a new treatment for stroke patients.”*

Importantly, the researchers from EuroHYP-1 are collaborating closely with European SMEs (Small and Medium-sized Enterprises), helping them to identify new product development ideas which can improve the delivery of therapeutic hypothermia. The therapeutic cooling devices developed, manufactured and marketed in Europe are included into the EuroHYP-1 trial and enable the effective delivery of the therapeutic cooling treatment.

The most active European SMEs with innovative technologies in the area of therapeutic cooling are two companies from Sweden: BrainCool AB (BrainCool.se), Quickcool (quickcool.se) and a company from Austria: EMCOOLS AG (emcools.com).

BrainCool represents a recently finalized, significant innovation: the inclusion of the cooling device into the EuroHYP-1 study protocol has been initiated in July 2016. The BrainCool system offers selective brain cooling, three different temperature zones and unique shivering detection. Shivering could be a side effect of cooling, which can be prevented with the BrainCool system. When shivering is imminent the BrainCool System can either alarm and/or slow down the coolant capacity of the system. The BrainCool System thus can place the patient just above the shivering trigger point and alert medical staff for further actions.

EMCOOLS provides easy to use and safe surface cooling pads for quick core temperature reduction. Both designs, Flex.PadTM and Brain.PadTM, are filled with the patented HypoCarbon® Technology, which is characterized by an outstanding cooling performance. The pads are very well tolerated in both, awake and unconscious patients and allow full mobility and patient access throughout the whole therapy.

QuickCool is a company with an innovative proprietary intranasal cooling method for targeted temperature management (TTM). The QuickCool cooling method is effective in cardiac arrest patients with a targeted body temperature of  $<36^{\circ}\text{C}$  (TTM), and is well tolerated in healthy conscious volunteers. The technology will be employed in awake stroke patients within the Eurohyp-1 project.

Since therapeutic cooling has the potential to be used on clinical diagnosis alone, this could have a great impact on acute stroke treatment. In contrast to thrombolysis, therapeutic cooling could then be initiated before brain-imaging studies, thus cooling for patients with acute stroke could be initiated by paramedics at first contact or as soon as the patient is received in the emergency room or even in the emergency medical ambulance cars. The EMCOOLS products (see above) are especially suitable for use in emergency medical ambulance cars.

In contrast to other cardiovascular diseases - for example ischemic heart disease, in which even a serious case rarely affects cognitive and neurological functions - stroke can have devastating consequences not only for the victims themselves but also for their partners and their broader family. This is especially so in cases when the patient is left with severe disabilities. Such dramatic changes are estimated to impact over 300,000 families a year in Europe alone (Eurostat).

The EUROHYP-1 consortium brings together leading European experts in statistical design and analysis, therapeutic hypothermia, health economics and trial execution (implementation and monitoring) as well as European patient and family advocacy groups. The EUROHYP-1 research programme is endorsed by the leading European and Global scientific community and European patient advocacy networks: the European Stroke Organisation (ESO), Stroke Alliance for Europe (SAFE), World Stroke Organisation (WSO), European Federation of Neurological Societies (EFNS), and also an indirectly impacted research organisation, the European Space Agency (ESA) - involved due to the interest in human hibernation studies necessary for organizing long-haul space travels, and the interrelation of therapeutic cooling with hibernation itself.

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