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Two Highly-Required Pionic Treatment in the Field of Vascular Neurology: Inducing Hypothermia in Stroke Victims Could Dramatically Boost Survival Rates, New Research Reveals

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Stroke is the second largest killer in the world after ischemic heart disease and currently there are a very limited number of treatments available when it hits. Now, scientists have found compelling evidence that cooling patients suffering from ischemic stroke by just a few degrees might not just greatly improve survival rates but also reduce the risk of long term disability.

Leading scientists meeting in Brussels on January 24 to review the latest scientific evidence were calling for the roll out of a large international, multicentre, phase III clinical trial that has the potential to bring concrete benefits to patients and to society within a short timeframe, but which needs EU funding to help it get off the ground. Their findings are contained in a report, "The use of therapeutic cooling to improve survival rates - proposal for trial", which was issued at the conference.

The consortium led by EuroHYP/www.eurohyp.org/and with the support of ECRIN, the European Clinical Research Infrastructures Network, proposes a unique interdisciplinary research program performed via the participation of leading European experts and stakeholders and the collaboration of scientists from the USA and Australia.

The internationally known leaders involved in the EuroHYP consortium represent a whole spectrum of scientific domains, from statistical design and analysis, stroke trial design, therapeutic hypothermia, ultrasound monitoring, imaging, biomarkers, health economics, and trial execution (implementation and monitoring). Moreover - beyond the academic experts - European patient and family advocacy groups and SMEs will be also actively involved in the implementation of the proposed research programme. Companies such as EMCOOLS, Elvido Medical Technology, QuickCool, Proteome Sciences, Randox Laboratories, Flowlab and GABO: mi, etc. are developing specific technologies, IT solutions and services. The project will be led overall by EuroHYP as a central coordinating hub. However, the key components of the implementation of the trial will be directed and coordinated by dedicated experts, teams, and organizations associated to universities, university hospitals, and other related entities in Europe - all with ample experience in similar research programs.

"Stroke is a major killer" says Dr Malcolm Macleod, Reader and Head of Experimental Neuroscience at the Centre for Clinical Brain Sciences at the University of Edinburgh, and Chief Investigator of HAIST, a pilot study of therapeutic hypothermia in acute ischemic stroke. "Every day 1,000 Europeans die from stroke - that's one every 90 seconds - and about twice that number survive but are disabled. Our estimates are that hypothermia might improve the outcome for more than 40,000 Europeans every year". Speaking for EuroHYP, a network which brings together the leading academic experts from Europe, along with patient groups and representatives of European industries, he said "The preliminary evidence is all there - now it is time for Europe to act". Therapeutic hypothermia, or cooling, is already used effectively in reducing ischemic brain injury following cardiac arrest and birth injuries. It acts by inducing a kind of hibernation in the brain, reducing the need for oxygen and preventing further damage. The technique is also being watched with interest by the European Space Agency because of its possible applications for the future of long distance space travel.

EuroHYP, in collaboration with the clinical trial units of universities, including Copenhagen/Malmø, Edinburgh, Glasgow, Utrecht, Erlangen and Helsinki, has become the driving force behind an international consortium that is bringing together the expertise and synergies essential for the large scale trial. "The objective is the full scientific testing of the promising experimental methodologies around therapeutic cooling in 1,500 patients

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with acute ischemic stroke, with particular focus on those who currently do not have access to a truly effective treatment or who exhibit limited response to the existing, standard interventions" says 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.

The PISCES (Pilot Investigation of Stem Cells in Stroke) study of ReNeuron Group plc's ReN001 therapy is the world's first fully-regulated clinical trial of a neural stem cell therapy for disabled stroke patients. Stroke is the third largest cause of death and the single largest cause of adult disability in the developed world. The therapy involves the introduction of neural stem cells into the brains of patients who have been affected by strokes with the aim of repairing damage and improving mental and physical function. The study, which is being conducted at the Institute of Neurological Sciences in Glasgow's Southern General Hospital under the supervision of experts from the University of Glasgow, has been cleared by the national Data Safety Monitoring Board (DSMB) to advance to the next stage of evaluation, which will involve patients receiving a higher dose of ReN001.

The DSMB reviewed safety data from the first dose cohort of three patients treated with ReN001, each of whom who have been left disabled by an ischaemic stroke, the most common form of the condition. The first patient treated in the cohort was assessed at nine months post-treatment, the second patient at six months and the third patient at three months. Laboratory safety tests, neurological examinations and neuro-functional tests conducted thus far indicate that the ReN001 treatment is safe and well-tolerated at the initial dose.

The Principal Investigator for the trial is Professor Keith Muir, SINAPSE Professor of Clinical Imaging, Centre for Stroke Research, Institute of Neuroscience & Psychology at the University of Glasgow. Professor Muir said: "We are pleased that there have been no safety issues from the first dose cohort in the PISCES trial and we look forward to evaluating further patients at a higher dose. ReN001 has the potential to address a very significant unmet medical need in disabled stroke patients and I am pleased that our team is involved in this pioneering clinical trial." Prof Schwab believes that: "We know the financial situation is difficult, but based on current evidence the personal and economic benefits of avoiding stroke related death and disability means that the trial would pay for itself in less than a year. As the population ages this trial will become even more important, and a benefit of cooling demonstrated in the proposed study will set the stage for future studies with hypothermia, extending the eligibility of the treatment to even greater number of patients."

However, according to Dr Macleod, the scientific know-how and technical and methodological expertise required are not available in any single European Member State. "The only way to create a successful program was to establish a Europe-wide research collaboration," he said. "That's what we have done. The stage is set". The number of hospitals participating is expected to be around 80 in total, from 21 countries in Europe, the countries being: Germany, Italy, UK, France, Spain, Poland, Denmark, Sweden, Finland, Netherlands, Croatia, Belgium, Estonia, Greece, Hungary, Ireland, Lithuania, Luxembourg, Norway, Portugal and Turkey.