

## **Multicenter clinical trial for hypothermia treatment of stroke patients obtain funding of MEUR 15**

### **Dignitanas subsidiary Brain Cool AB technology to be evaluated**

The academic partner group EuroHYP, the European Stroke Research Network for Hypothermia that Dignitana formed collaboration with during 2011, have proposed a large, multicentre clinical trial which will assess mild hypothermia as a novel treatment for ischemic stroke. The trial have now received funding from the European Union with a total project cost of 14 970 000 €.

The large multicentre clinical trial will assess mild hypothermia as a novel treatment for ischemic stroke.

Stroke is the second cause of death world-wide and the second cause of lost disability-adjusted life years in high-income countries. Stroke incidence rises exponentially with age, so its social and economic burden will grow with the ageing of the European population. Current treatment options for the 80 to 85% of all strokes due to cerebral ischaemia - around 900,000 events in Europe every year, or one every 40 seconds - are extremely limited.

Systematic review of experimental studies suggests that hypothermia is the most promising intervention identified to date.

Dignitana have through its subsidiary been focusing on development of cooling technologies with the primary aim to cool stroke patients for creating neuroprotection.

Even small medical advantages on these two enormous patient groups will give large health economic gains for the society as well as the potential for necessary technology to be adopted on all hospitals with emergency care programs fore these patients.

Cooling has so far been tried on stroke-patients only in a few and relatively small studies, but this large study including more than 1 500 patients will be paramount to establish cooling as part of the standard treatment for patients with acute ischemic stroke.

#### **Martin Waleij Chief Executive Officer comments;**

“Firstly, I think this study is a very good step for improving the treatment of stroke patients both in terms of reducing death, and for reducing disability and improving the quality of life for the survivors of stroke.”

“Secondly, this confirms and acknowledges that our company is on the right track being part in this major project with our cooling device”

“This is a very good step forward for our development project, It is strong evidence for that the clinical development we have delivered so far is of high value, making it possible for us to be part of this project”

“We believe that our approach of starting the cooling in an early phase and using selective brain cooling with the aim to lower the brain temperature without lowering the body temperature more than marginally, has considerable advantages. Thereby we avoid potentially dangerous consequences for the immune system and for raising the risk of bleeding and infection.

“Our new semi-portable cooling technology will be used in the trial from late 2012 by a number of leading European Stroke institutions. In addition we expect to obtain further international clinical evidence for the benefits of our cooling technology from other clinical studies, that already are on their way during 2012.

“The results from the completed clinical trial will form the reference of cooling of stroke patients as part of the standard treatment.”

“The aim of our development of a semi-portable cooling device with Partnertech is to adapt the product to several indications, where the primary indication will be stroke and cardiac arrest.”

“The cooling device will also be adapted to cooling on neonatal babies, and for homecare infusion in oncology patients.“

“This is a great step in the long term plan to create not only a quality-of-life oncology company, but to form the medical cooling company we now see develop very well.”

For further information

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