



*Interviews Available on Request*

**Caren Browning**

The Morris + King Company

00 1 212 561-7464

[Caren.Browning@morris-king.com](mailto:Caren.Browning@morris-king.com)

**Martin Waleij**

CEO Dignitana

+46 733 93 70 76

[Martin.Waleij@dignitana.com](mailto:Martin.Waleij@dignitana.com)

**Eleanor Cowie**

Press & PR Officer, Univ. of Edinburgh

0131 650 6382

[Eleanor.Cowie@ed.ac.uk](mailto:Eleanor.Cowie@ed.ac.uk)

## **Brain Cool AB and University of Edinburgh Announce Phase One Clinical Trial to Test New Medical Brain Cooling Device**

### **Advanced System Holds Promise as Potentially Life-Saving Early Intervention for Stroke Patients**

**LUND, Sweden and EDINBURGH, Scotland (March 4, 2013)**—Brain Cool AB announced today that its new medical device for therapeutic brain cooling is being tested in a clinical trial at the University of Edinburgh. Developed initially for use with stroke patients, Brain Cool has promising implications for use in other patient groups as well. In this University of Edinburgh clinical trial, the device is being tested on healthy volunteers to measure efficacy of brain cooling rates.

Brain Cool uses a patented cooling method developed by Dignitana, a world leader in scalp-cooling technology and the maker of the DigniCap™ System for the prevention of chemotherapy-related hair loss. The advanced technology used in the new Brain Cool System allows cooling of the neck, which helps to speed perfusion and cooling of blood before it reaches the brain—a critical intervention for patients suffering from stroke. Brain Cool is the first medical device now available for clinical use to be tested for this purpose.

Therapeutic hypothermia, or cooling, lowers a patient's body temperature to help reduce the risk of injury to the brain following a period of insufficient blood flow due to an ischemic event such as cardiac arrest, stroke, traumatic brain injury or neonatal asphyxia. A reduction of body temperature to 35 °C induces a kind of hibernation status of the brain that may help protect the brain from stroke-induced damage.

"Every day 1,000 Europeans die from stroke—that's one every 90 seconds—and about twice that number survive but are disabled," said Dr. Malcolm Macleod, Professor of Neurology and Translational Neuroscience and Head of experimental neuroscience at the Centre for Clinical Brain Sciences at the University of Edinburgh.

Stroke is the second largest cause of long-term disability in developed countries, and the second cause of death worldwide. Even in this advanced medical age, stroke patients today have little or no access to immediate and effective therapy, thus, tragically, two thirds of stroke patients remain disabled or die following a stroke.

"A further advantage," Dr. Macleod adds, "is that cooling can be used in the vast majority of stroke patients. This is not the case for clot-bursting drugs, which can be used only in about one of five patients. The technology from Brain Cool AB is particularly interesting due to the possibility of using selective brain cooling only, and that it can be initiated at a very early phase. In time it might be possible to initiate brain cooling in the back of ambulances."

Results from previous pilot studies suggest that even a small reduction of the brain temperature—as little as 1°C, some scientists believe—could be beneficial in treating stroke patients, and may even contribute to significantly reduced mortality rates and improved quality of life for stroke survivors.

"The number of patients who could potentially be helped by brain cooling is substantial," said Martin

Waleij, CEO of Dignitana AB and Chairman of the Board for Brain Cool AB. “We expect the findings of this clinical trial at the University of Edinburgh to firmly confirm our pilot evaluations and provide solid clinical evidence for the use of medical cooling primarily in stroke patients. In addition to the indication for use in stroke, new patent applications have also been submitted in the US complementary to the existing worldwide patents of Dignitana AB.”

Brain Cool’s ease of use provides a significantly more efficient and tolerable therapeutic cooling method than other devices currently being tested for cooling the brain. Unlike these other therapies, Brain Cool offers flexibility and ease of use for both patient and clinician. The body remains completely free and unrestricted during use, and most patients are awake or resting calmly during treatment.

An advanced Brain Cool model that can be easily transported is currently in development in addition to the standard Brain Cool System now available. **Portability and ease of use could make this new medical device particularly advantageous for stroke patients, for whom immediate intervention can be critical.**

“With nearly 150,000 people suffering a stroke each year in the UK, the patient need for measures like brain cooling that offer protection of the brain is obvious,” adds Waleij. “Saved lives and improved quality of life for surviving patients mean improved health and economic gains for all of society. We are opening the door to a new world of advanced healing that could improve quality of life for people with stroke, traumatic brain injury, cardiac arrest, and neonatal asphyxia.”

#### **About University of Edinburgh Centre for Clinical Brain Sciences**

The Centre for Clinical Brain Sciences (CCBS) was established in 2004 and is a part of University of Edinburgh. It is a multidisciplinary translational "centre without walls" combining basic and applied research to study the causes, consequences and treatment of major brain disorders. An explicit aim of the Centre is to discover and deliver novel therapies for brain disorders.

#### **About Brain Cool AB (publ)**

Brain Cool AB is a wholly-owned subsidiary of Dignitana AB, with a focus on medical cooling for therapeutic results. Brain Cool is being clinically tested in Sweden and the United Kingdom. A patent has been filed and is pending in the United States.

#### **About Dignitana AB (publ)**

Dignitana AB, is a Swedish medical device company focused on innovative technologies in the area of medical cooling. Dignitana is the creator of **DigniCap™** the patented medical device for preventing hair-loss in chemotherapy patients, which utilizes a standardized, controlled and reliable process for cooling of the scalp in order to protect hair follicles during chemotherapy transfusions. Dignitana is listed on the OMX NASDAQ Stockholm First North.

For more information visit [www.dignitana.com](http://www.dignitana.com)

###