CEFALY®

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New Study Shows CEFALY Returns Normal Metabolic Activity to Brain Areas in Migraine Patients

FDA-approved device to prevent migraines, reveals results from a new clinical PET scan trial that shows it returns normal brain metabolism to specific cortical zones

NEW YORK, June 1, 2015_ CEFALY Technology, the creators of the first FDA-approved transcutaneous electrical nerve stimulation device specifically authorized for use prior to the onset of migraine pain, has released significant data from a new PET trial showing that the Cefaly device returns normal metabolic activity to the areas in the brain in migraine patients, namely the orbitofrontal cortex and rostral cingulate.

The Positron Emission Tomography (PET) scan, which is an imaging test of the brain, used a radioactive substance called a tracer to show how the brain and its tissues are working under the influence of a Cefaly®.

“This is a major breakthrough in understanding the mechanism of action of the device on the central nervous system,” said Dr. Pierre Rigaux, chief executive officer of CEFALY Technology, the maker of the device. “It will help us take developments in this non-invasive, drug-free, technology even further.”

The study, which was conducted as part of EUROHEADPAIN, a major European research project focused on migraines, looked at 28 patients with at least four migraines per month. These patients brain activities’ were monitored as they used the Cefaly once per day for 20-minutes for a period of three months. The goal of the trial was to better understand and identify the short and medium term metabolic changes in the brain areas of those afflicted with migraines -- the orbitofrontal cortex and the rostral cingulated, which are especially involved in decision-making and emotional behavior. In patients with migraines these areas tend to be sub-metabolic in comparison to patients without migraines.

"The modifications observed through the PET scan reinforce the strong clinical data on safety and efficacy that led to the FDA approval,” said Rigaux.

The results were presented at the EUROHEADPAIN - Midterm Meeting at the International Headache Society Congress in Valencia, Spain, last month. The International Headache Society is the world's leading membership organization for those with a professional commitment to helping people affected by headache.

In March 2014, the FDA approved the prescription-only, headband-like, device that uses tiny electrical impulses to stimulate the trigeminal nerve to reduce the frequency and intensity of migraines. At that time, it reached its decision using data from a randomized double blinded clinical trial implemented in five university clinics in Belgium; as well as a patient satisfaction study of 2,313 Cefaly® users in France.

About CEFALY Technology

CEFALY Technology is a Belgium-based company, with US offices based in Darien, Connecticut, specializing in electronics for medical applications. It has developed external cranial stimulation technology for applications in the field of neurology; in particular for treating migraines. http://www.cefaly.us/