Device Approved For Treatment of Chronic Migraine in Europe

Genesis™, an implanted neurostimulation device, receives European CE Mark approval for the treatment of chronic migraine.

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September 7, 2011 –Genesis™, a small, implantable device stimulating the occipital nerves, for the treatment of intractable chronic migraine, received European CE Mark of approval, announced St. Jude Medical, Inc., the developer of the device, today.

Peripheral nerve simulation appears to be an effective strategy for the treatment of pain associated with migraine when other therapies have failed. Genesis™ is a neurostimulation device that works by delivering mild electrical pulses to the occipital nerves located at the back of the head. The pulses generated by the device are sent to the occipital nerves through thin lead wires implanted under the skin, contacting the nerves. Stimulating the occipital nerves with an electric signal alters the sensation of pain. The device has been previously approved for use in countries around the world as a spinal cord stimulator for alleviation of pain in the trunk and limbs, and pain from back surgeries that have failed.

A large clinical study funded by St. Jude Medical, Inc. tested the efficacy of the Genesis™ treatment. The results of the study were presented at the International Headache Congress in Berlin, Germany in June 2011, but have not yet been published in medical journals.

The controlled, double-blind, randomized study involved 157 patients suffering from chronic migraine. Patients reported 26 days of headaches per month, on average, before treatment. Participants were randomized to an active or a control group for the first 12 weeks of the study. The active group started treatment from the outset of the study, while the control group had its devices activated at week 12. Data were collected at 12 weeks with a follow up at 12 months.

Results showed a reduction of the number of headaches by 7 days per month in the active group at the 12 weeks study point. By contrast, the control group reported headache reduction by only 1 day per month.

Patients in the active group reported an improvement of 41% in their disability, compared to 13% in the control group. Additionally, at one year, 68% of patients reported an improvement of their quality of life, and 67% of patients reported being satisfied with the procedure. These numbers are based on various migraine assessment measures, including patient migraine diaries and Migraine Disability Assessment (MIDAS) questionnaire. The treated patients described only 1% adverse events related to the treatment.

The National Headache Foundation classifies a migraine as chronic if it occurs for more than 15 days per month for at least three months. In chronic cases the migraine is refractive to the action of three or more preventive drugs. For such patients alternatives to drug therapies are needed, and neurostimulation seems to be beneficial.

Will US patients with intractable chronic migraine gain access to occipital nerve stimulation therapies? Denise Landry, the St Jude Medical's spokeswoman noted that the company "will begin discussions with regulatory authorities in other markets, including the US Food and Drug Administration (FDA), later this year to determine next steps". Reports by analysts from earlier this year, however, suggested that the FDA would like to see a higher statistically significant response at the 50% pain reduction threshold. Results at the 40% pain reduction threshold were satisfactory ($P<0.05$).

The US-based company, Medtronic, is testing clinically a similar device for the treatment of chronic migraine headache. A phase I trial was completed in May 2011 but its results have not yet been announced.