Medtronic News

Newly Published Data Show Occipital Nerve Stimulation May Be a Promising New Therapy for Chronic Migraine

Initial Results Suggest ONS Warrants Further Study for Control of Chronic Migraine

MINNEAPOLIS, Sep 17, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) announced that data from a multicenter, prospective, randomized, blinded, feasibility trial published today show promise for occipital nerve stimulation (ONS) for treating medically refractory chronic migraines and support the need for further controlled study of the treatment. The study, called Occipital Nerve Stimulation for the Treatment of Intractable Migraine (ONSTIM), included severely debilitated patients who had regularly experienced 15 or more headache days per month that were not responsive to currently available medical therapies. Findings were published in the international headache journal, *Cephalalgia*, and represent the first publication of randomized, controlled data examining ONS for the treatment of chronic migraine. These preliminary data will form the basis for a pivotal clinical trial to demonstrate safety and effectiveness and support market authorization.

The ONSTIM study, sponsored by Medtronic and conducted under an investigational device exemption (IDE), was an initial study to determine whether a well-designed, placebo-controlled study could provide insights into the potential benefits and risks of ONS therapy. Electronic diary data was collected from 66 patients from nine centers who were followed for three months. Of the patients who received adjustable stimulation (n = 28), 39 percent (11 patients) obtained at least a 50 percent decrease in headache days per month or at least a three-point decrease in overall pain intensity from baseline. Additionally, patients in the adjustable stimulation group experienced an average of 27 percent (+/- 44.8 percent, standard deviation) fewer headache days per month at the third month of ONS treatment compared to before treatment.

"Migraine affects more than 28 million people and for up to 14 percent of those people, their migraines become chronic and can severely affect quality of life," said Dr. Joel R. Saper, M.D., founder and director of the Michigan Head Pain and Neurological Institute, and principal investigator for the ONSTIM study. "The patients in this study had been unsuccessful in controlling their debilitating, frequent migraines. The positive impact ONS had on the migraines in these severely impaired study participants is promising and supports the need for ongoing study of this therapy."

In the study, thin leads were placed under the skin near the occipital nerves, which originate in the spinal cord and branch out across the back of the head carrying sensory signals from that region to the brain. The leads were connected to an implanted neurostimulator that delivered controlled electrical pulses to the occipital nerves. Patients were randomized to three groups: a group that received a neurostimulator with the ability to control the level of stimulation, a group that received a neurostimulator as part of a device control group, or a group that received only medical management instead of an ONS implant. These patients had experienced migraine headaches for an average of 24 years and chronic migraines for an average of 11 prior to study enrollment.

The most common adverse device event was lead migration, which did not lead to long-term complications. Data from this study provide information from which improvement in device and surgical techniques can be made in future studies. In addition to evaluating the efficacy of ONS therapy, the ONSTIM trial was designed to follow patients out to three years related to safety. At the time of publication, long-term follow-up visits were still being completed.

"Medtronic is a leader in developing therapies for chronic pain and we remain committed to developing new therapies where there is a need, as is the case for chronic migraine." said Tom Tefft, senior vice president and president of the Neuromodulation business at Medtronic. "We are using the outcomes from this trial to guide our pursuit of a well-designed pivotal clinical trial that will provide a high level of evidence to support the therapy with the hope that it will become an option for patients who are

suffering from debilitating migraines."

Medtronic's Leadership in Neuromodulation

Medtronic developed and leads the field of neuromodulation, the targeted and regulated delivery of electrical pulses and pharmaceuticals to specific sites in the nervous system. Other Medtronic neurostimulation technologies already have gained significant medical acceptance for the management of symptoms of chronic back and leg pain, deep brain stimulation for the treatment of Parkinson's disease and essential tremor and sacral nerve stimulation for the treatment of the symptoms of overactive bladder and urinary retention. To date, more than 500,000 people worldwide have received Medtronic Neuromodulation therapies.

About Chronic Migraine

More than 28 million Americans - 70 percent of whom are women - suffer from migraines and lose about 157 million workdays each year. In the Global Burden of Disease Study, published by the World Health Organization in collaboration with the World Bank and the Harvard School of Public Health, severe migraine was ranked in the highest of seven disability classes along with psychosis, dementia and quadriplegia. Despite multiple drug treatments and noninvasive alternative therapies, approximately 3 - 14 percent of migraine sufferers progress to a chronic state and can become intractable to medical therapies. Some of these patients could be candidates for ONS therapy if further studies demonstrate the safety and efficacy and lead to commercialization of this therapy.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

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