Medtronic News

Pivotal Study of Medtronic Deep Brain Stimulation Therapy Shows Long-Term Reduction in Seizure Rate in Patients with Severe Epilepsy

Ongoing Research Focuses on Optimizing DBS Therapy for Patients

MINNEAPOLIS--(BUSINESS WIRE)--Dec. 6, 2009-- Long-term data from an investigational study of Deep Brain Stimulation (DBS) Therapy for Epilepsy was released this week by Medtronic, Inc. (NYSE:MDT) at the American Epilepsy Society Meeting (AES) in Boston. The results of the study show improvement over time with median (mid-point) reduction in seizure frequency of 41 percent at one year, 56 percent at two years, and 68 percent at three years of DBS therapy, in conjunction with antiepileptic medications, compared to baseline. Of the original 110 patients who received DBS implants in the trial, 91 remain active in the study, including some who have received DBS therapy for more than five years. At the time of this data analysis, 102 patients had completed two years and 57 had completed three years of therapy. In addition, 14 patients (13 percent) experienced seizure free intervals ranging from six months to more than four years.

The study, known as SANTE® (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy), is a prospective, randomized, double-blind pivotal study to evaluate the use of DBS therapy for patients with medically refractory epilepsy with partial-onset seizures, a form of epilepsy that does not respond well to antiepileptic drugs. Medtronic DBS Therapy for Epilepsy is investigational. A premarket approval (PMA) application has been submitted to the U.S. Food & Drug Administration (FDA) seeking approval to market Medtronic DBS Therapy for Epilepsy in the United States.

The types of adverse events reported in the study were consistent with known adverse events associated with epilepsy and implanted DBS systems. There were no serious unanticipated device-related adverse events. At the conclusion of the unblinded phase of the study (first 13 months), 4.2 percent of adverse events (a total of 34 events) were serious and device-related. That rate declined over time. Of the 34 events, the most frequent serious device-related events were lead(s) not within the target (nine events) and implant site infection (eight events). Depression and memory impairment were reported more frequently in active stimulation patients compared to no stimulation (controls) although objective neuropsychological assessment did not show any statistical differences between active or no stimulation (control) groups.

“At the end of the blinded phase of the study, the active group had a statistically significantly higher reduction in seizure frequency compared to the control group. Most encouraging is that the benefit grew over time with a median reduction compared to baseline of 56 percent and 68 percent after two and three years of DBS therapy,” said Robert Fisher, M.D., professor of neurology and director of Stanford Epilepsy Center and principal investigator for the SANTE study. “This was a rigorously designed, randomized, blinded trial, with good capture of long-term data in the open-label phase. Based on the outcome of the study, DBS therapy holds promise for patients with epilepsy who are severely affected and have not had success with other treatments, including medications, and in some cases, vagus nerve stimulation or even surgery.”

The SANTE study involves stimulating the left and right anterior nucleus of the thalamus – the brain’s central message and relay station – with Medtronic DBS Therapy for Epilepsy in conjunction with epilepsy medications. Patients in the study have had epilepsy for an average of 22 years and 54 percent of the 110 implanted patients had previously undergone resective surgery and/or vagal nerve stimulation therapy. Benefit was seen in patients with prior history of vagal nerve stimulation or previous epilepsy surgery as well as patients without such history.

Ongoing Research

Building on more than a decade of research in this area,Medtronic also shared highlights from other ongoing research efforts focused on understanding how to optimize DBS therapy. Smaller studies focused on establishing the mechanism of action in

DBS therapy for epilepsy and on the development of algorithms for optimizing therapy to individual patient needs. In addition to the clinical data from the SANTE trial, these ongoing research efforts provide insights into how the application of DBS therapy for epilepsy will continue to advance in the future.

“We are very encouraged by the SANTE trial results, which offer hope to patients with a severely debilitating chronic condition,” said Tom Tefft, president of the Neuromodulation business and senior vice president atMedtronic. “This study and our other research efforts focused on optimizing therapy reinforce our commitment to providing significant clinical evidence for DBS therapy for epilepsy as well as to advancing the therapy and long-term outcomes for patients.”

About SANTE

The investigational study collected data from 110 patients who were implanted with a Medtronic DBS system at 17 U.S. centers. Study participants had partial-onset epilepsy, had failed to see benefit from at least three antiepileptic drugs and had an average of six or more seizures per month. All patients continued to receive epilepsy medications while participating in the study. After the three-month, double-blind phase (comparing the active stimulation group to the no stimulation control group), all patients received neurostimulation within pre-defined parameters for nine months, followed by a long-term follow up phase where they continued to receive neurostimulation and physicians were allowed to change stimulation parameters. Full results from the blinded phase of the trial were presented at the AES Meeting in December 2008.

Other Medtronic neurostimulation therapies already have won significant medical acceptance for the management of symptoms of advanced Parkinson’s disease, essential tremor, and chronic back and leg pain. Medtronic, in collaboration with leading physicians from around the world, has pioneered the use of neurostimulation for treatment of these conditions and continues to pursue research for other applications.

About Epilepsy

According to the Epilepsy Foundation, epilepsy and seizures affect more than three million Americans of all ages, at an estimated annual cost of $12.5 billion in direct and indirect costs. Despite trying a range of treatment options, about one-third of people with epilepsy cannot adequately control their seizures or tolerate other available therapies. The unpredictability of seizures significantly affects a patient’s life and daily activities.

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.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic’s Annual Report on Form 10-K for the year ended April 24, 2009. Actual results may differ materially from anticipated results.

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