Medtronic News

New Data in the New England Journal of Medicine Show Medtronic Deep Brain Stimulation Provides Sustained Motor Function Improvement in Parkinson's Disease

MINNEAPOLIS, Jun 02, 2010 (BUSINESS WIRE) --In the largest, randomized, controlled study of deep brain stimulation (DBS) for Parkinson's disease, Medtronic DBS Therapy was shown to improve motor function for up to two years in patients with advanced Parkinson's disease, showing equally strong efficacy for the two most common surgical targets used for the therapy. The study, conducted at seven Veterans Affairs and six university hospitals with participation from 299 patients, compared the 24-month results of patients assigned randomly to receive DBS via one of the two common targets in the brain - the subthalamic nucleus (STN) or globus pallidus interna (GPi). The findings are published in the June 3 issue of The New England Journal of Medicine.

"These long-term data show that DBS provided sustained improvement in motor function and symptom control and increased quality of life in patients with advanced Parkinson's disease, with no statistical difference in efficacy between the two primary surgical sites," said Kenneth A. Follett, M.D., Ph.D., Iowa City VA Medical Center and professor and chief, Division of Neurosurgery at University of Nebraska Medical Center. "Clinicians should be assured that both of the commonly used stimulation locations are equally viable targets for DBS, which has become the surgical procedure of choice for treatment of advanced Parkinson's disease."

The results of the study showed that improvement in motor function, based on the Unified Parkinson's Disease Rating Scale (UPDRS) Part III, did not differ between the STN and GPi patient groups. Both groups experienced a significant improvement in average UPDRS motor scores at two years. Daily time, as reported by patient motor diaries, spent in the "on" state (classified as good symptom control and unimpeded motor function) increased, and daily time in the "off" state (classified as poor symptom control and motor impairment) decreased similarly in both groups. Furthermore, quality of life improved in both STN and GPi patients on six of eight subscales measured by the Parkinson's Disease Questionnaire-39 (PDQ-39).

In the study, serious adverse events (SAEs) occurred in approximately half of both GPi and STN patients, with the most common SAE among both groups being surgical site infection, which occurred in less than 10 percent of each group. One death was reported in the study related to the surgical procedure (intracranial hemorrhage) and one GPi patient committed suicide. Ninety-nine percent of the SAEs were resolved by the 24-month study follow-up.

"Data collected from this study demonstrate not only the long-term efficacy of Medtronic DBS Therapy for Parkinson's disease but also the positive impact the therapy has on patients," said Tom Tefft, president of the Neuromodulation business and senior vice president at Medtronic. "These results are representative of Medtronic's commitment to provide innovative, long-term solutions for patients with chronic disease."

About the study

The first phase of the study compared best medical therapy (BMT) to DBS, in which patients were randomized to BMT (134 patients) or bilateral DBS (121 patients) plus medication. In the DBS group, patients were further randomized to receive stimulation with Medtronic's Kinetra(R) neurostimulator at either the subthalamic nucleus (60 patients) or globus pallidus (61 patients). Study results from the first phase were reported at six months and showed that DBS therapy provides a mean 4.6 hours of additional time in the "on" state without troublesome dyskinesias versus BMT alone. These results were published in the January 2009 edition of the *Journal of the*

American Medical Association.

In the second phase of the study comparing the two stimulation targets, all patients were randomized to STN or GPi. Patients returned to their study site at 3, 6, 12, 18, and 24 months. Primary outcome of the second phase was UPDRS Part III blinded assessment of motor function between STN and GPi patient groups in the on stimulation/off medication condition. Secondary outcomes included self-reported function, quality of life, neurocognitive function and adverse events.

The study was conducted under FDA Investigational Device Exemption (IDE) regulations and sponsored by the Veterans Affairs (VA) Cooperative Studies Program in partnership with the National Institute of Neurological Disorders and Stroke (NINDS) and Medtronic, Inc. (NYSE: MDT).

About Medtronic DBS Therapy
Medtronic, in collaboration with leading physicians around the world, pioneered DBS therapy. To date, more than 75,000 people worldwide have received Medtronic DBS Therapy.

Medtronic DBS Therapy is approved by the U.S. FDA for the treatment of the disabling symptoms of essential tremor and advanced Parkinson's disease. The therapy is approved under Humanitarian Device Exemptions (HDEs) for the treatment of dystonia, and chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD). DBS therapy is reversible and can be programmed and adjusted non-invasively (without surgery) by a trained clinician to find the most appropriate type and amount of stimulation for each patient to maximize symptom control and minimize side effects.

Medtronic has been involved in more than 1,500 clinical studies and continues to pursue additional studies today to evaluate the promise of this therapy for other chronic, debilitating neurological conditions.

About Parkinson's Disease
About 1.5 million Americans currently have Parkinson's disease, with 60,000 new cases diagnosed each year. Although symptoms vary from person to person, Parkinson's disease is generally characterized by two of four major features: shaking while a limb is at rest, slowness of movement, rigidity or the limbs, or poor balance. Common treatments include medication such as levodopa, which converts to dopamine in the brain. There is no known cure for Parkinson's disease.

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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