Medtronic News

First Publication of Data from Pivotal Clinical Trial for Medtronic Deep Brain Stimulation Therapy for Epilepsy Published Today in Epilepsia

MINNEAPOLIS, Mar 18, 2010 (BUSINESS WIRE) -- Medtronic, Inc. (NYSE:MDT) today announced that a landmark publication highlighting results from the pivotal study for Medtronic Deep Brain Stimulation (DBS) Therapy for epilepsy, known as SANTE(R) (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy), was published online today in the medical journal, Epilepsia. The SANTE study, sponsored by Medtronic, is the largest and most rigorous clinical study of DBS therapy for epilepsy in adults with medically refractory epilepsy with partial-onset seizures. Today's publication includes results from the blinded phase of the study and through two years of therapy. Medtronic DBS therapy is under review by the U.S. Food and Drug Administration (FDA).

"The SANTE trial was a rigorous, well-designed, blinded trial with long-term follow up in an 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," said Robert Fisher, M.D., professor of neurology and director of Stanford Epilepsy Center, principal investigator for the SANTE study and lead author of today's publication.

Regulatory Status

Medtronic DBS Therapy for Epilepsy is investigational and uses a pacemaker-like device to deliver individualized, targeted and precise electrical stimulation to a specific target in the brain called the anterior nucleus of the thalamus, which is part of a circuit involved in seizures. Medtronic has submitted a supplemental Pre-Market Approval (PMA) application for DBS Therapy for Epilepsy that remains under review by the FDA. On March 12, 2010, the FDA Neurological Devices Panel of the Medical Devices Advisory Committee voted to recommend U.S. FDA approval with conditions for DBS therapy for epilepsy as adjunctive treatment for partial-onset seizures in adults with medically refractory epilepsy.

"DBS therapy for epilepsy is another important example of Medtronic's commitment to develop innovative solutions for patients with chronic, debilitating diseases," said Tom Tefft, senior vice president and president of Medtronic's Neuromodulation business. "We will work closely with the FDA to address the conditions of approval proposed by the FDA panel so that we can make this therapy available to patients with epilepsy who have limited treatment options."

About Medtronic DBS Therapy

Medtronic DBS Therapy is currently approved by the FDA for the treatment of the disabling symptoms of essential tremor and advanced Parkinson's disease. The therapy is approved under a Humanitarian Device Exemption (HDE) for the treatment of dystonia, and chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD). The 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. More than 75,000 people worldwide have received Medtronic DBS Therapy.

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 periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

SOURCE: Medtronic, Inc.

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