Medtronic News

Medtronic Receives FDA Approval for Deep Brain Stimulation Therapy for Medically Refractory Epilepsy

7-Year Data from the SANTE Trial Showed Median Seizure Frequency Reduction of 75 percent in Patients with Drug-Resistant Epilepsy with Partial-Onset Seizures Receiving DBS Therapy.

DUBLIN - May 1, 2018 - Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced that the U.S. Food and Drug Administration (FDA) has granted premarket approval for Medtronic's Deep Brain Stimulation (DBS) therapy as adjunctive treatment for reducing the frequency of partial-onset seizures, in individuals 18 years of age or older who are refractory, or drug-resistant, to three or more antiepileptic medications. DBS therapy for epilepsy delivers controlled electrical pulses to a target in the brain called the anterior nucleus of the thalamus (ANT), which is part of a network involved in seizures.

According to the Epilepsy Foundation, 3.4 million individuals in the United States have epilepsy. Antiepileptic drug (AED) medication is the primary treatment to control seizures; however, up to one third of individuals with epilepsy have seizures that do not successfully respond to AEDs.

"Many patients in the United States with severe epilepsy are not able to control their seizures with currently-available drugs and are not candidates for potentially curative surgery," said Dr. Robert Fisher, director of the Stanford Epilepsy Center, Stanford University, and lead principal investigator of the SANTE trial. "Epilepsy that is refractory to AED treatment is an unsolved problem, and DBS therapy will now serve as an important new treatment option, including for people with poorly localized or multiple regions of seizure origin."

The FDA approval is based on both the blinded phase and the 7-year follow-up data collected in Medtronic's clinical trial called SANTE® (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy). The SANTE trial was a prospective, randomized, double-blind pivotal study to evaluate the use of DBS therapy for patients with medically refractory epilepsy with partial-onset seizures, with or without secondary generalization, that were drug-resistant to three or more antiepileptic medications. The trial collected data from 110 patients who were implanted with a Medtronic DBS system at 17 centers located in the U.S.

Results include1-4:

- The median total seizure frequency reduction from baseline was 40.4 percent versus 14.5 percent for the placebo group at 3 months, and 75 percent at 7-years, with open-label ongoing therapy.
- Twenty subjects (18 percent) experienced at least one 6-month seizure-free period between implant and year 7, including eight subjects (7 percent) who were seizure-free for the preceding 2 years.
- Seizure severity and quality of life scales both showed statistically significant improvements from baseline at year 7.
- No significant cognitive declines or worsening of depression scores were observed through the blinded phase or at year 7. Improved scores were observed at 7-years on measures of executive functions and attention.

"We are very pleased to have completed the review process for DBS for Epilepsy with the FDA, and we are extremely grateful to the patients and their treating teams for their commitment to the SANTE trial and this therapy over many years," said Mike Daly, vice president and general manager of the Brain Modulation business, which is part of the Restorative Therapies Group at Medtronic. "We look forward to beginning the launch of this therapy in the U.S. during the course of this year."

About Medtronic DBS Therapy

DBS therapy uses a surgically implanted medical device, similar to a cardiac pacemaker, to deliver electrical stimulation to precisely targeted areas of the brain as adjunctive treatment for several neurological disorders. Medtronic DBS systems are the first and only approved for full-body MRI scans under specific conditions in the United States. Since 1997, more than 150,000 Medtronic DBS devices have been implanted worldwide for movement disorders and other indications.

In addition to medically refractory epilepsy, DBS therapy is currently approved in many locations around the world, including the

United States and Europe, for the treatment of the disabling symptoms of essential tremor and recent and longer-standing Parkinson's disease. Under Humanitarian Device Exemption (HDE) approvals in the United States, the therapy can also be used to treat chronic intractable primary dystonia and severe, treatment-resistant obsessive-compulsive disorder.

The FDA-approved indication for epilepsy is as follows: Bilateral anterior thalamic nucleus stimulation using the Medtronic DBS System for Epilepsy is indicated as adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications. The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness in patients who averaged six or more seizures per month over the three most recent months (with no more than 30 days between seizures) and has not been evaluated in patients with less frequent seizures.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 84,000 people worldwide, serving physicians, hospitals and patients in more than 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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.

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1 Fisher RS et al. Electrical stimulation of the anterior nucleus of thalamus for treatment of refractory epilepsy. Epilepsia. 2010 May; 51(5):899-908

2 Salanova V et al. Long-term efficacy and safety of thalamic stimulation for drug-resistant partial epilepsy. Neurology. 2015 Mar10; 84(10):1017-25.

3 Sandok E et al. Long term outcomes of the SANTE Trial: 7-Year Follow-Up. American Epilepsy Society Annual Meeting. 2016 Abst. 1.298.

4 Tröster AI et al. Memory and mood outcomes after anterior thalamic stimulation for refractory partial epilepsy. Seizure. 2017 Feb; 45:133-141.

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