Medtronic Announces U.S. Commercial Launch of Deep Brain Stimulation for Medically-Refractory Epilepsy

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Medtronic plc

With Official Launch and First Implant, Several Health Insurers Now Consider DBS Therapy for Epilepsy a Covered Indication

DUBLIN - February 20, 2019 - Medtronic plc (NYSE:MDT) today announced both the U.S. launch of Deep Brain Stimulation (DBS) for medically-refractory epilepsy and the first commercially implanted patient at Emory University in Atlanta, Ga. According to the Epilepsy Foundation, as many as 3.4 million Americans have epilepsy[1], with one-third estimated to be drug resistant.[2]

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. Recently, the U.S. Food and Drug Administration (FDA) granted pre-market approval for Medtronic DBS Therapy for Epilepsy 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. The approval was based on results from the SANTE® (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy) trial, wherein patients had a median seizure frequency reduction of 75 percent at seven years post-implant.

"The commercial availability of DBS provides an important surgical treatment option for patients who suffer from epilepsy and do not respond to medication," said Robert E. Gross, M.D., Ph.D., MBNA Bowman chair & professor, Emory University Department of Neurosurgery, neurosurgical primary investigator for the SANTE trial. "ANT DBS has been shown to significantly reduce the frequency and severity of seizures and improve quality of life out to seven years. The first patient implanted since commercialization is doing very well. While it has only been 2 months since the system was turned on, his frequency of seizures has declined by more than 50 percent, and we expect improvement to increase further with additional programming sessions."

"I have seen first-hand the negative effects of medication-resistant seizures in many of my patients - some are unable to hold a job or maintain a high quality of life," said Robert Fisher, M.D., director of the Stanford Epilepsy Center, Stanford University, and lead principal investigator of the SANTE trial. "I have also seen through my involvement in the SANTE trial how DBS reduced the number and often the severity of seizures. I am excited that this treatment is now available in the U.S. to help people with uncontrolled seizures."

With FDA approval and supporting clinical evidence, several health insurers have updated their policies to include ANT DBS therapy for epilepsy as a covered indication. This includes Aetna, which covers patients across the U.S.; Blue Cross Blue Shield CareFirst, which covers patients in Washington D.C., Maryland, and Virginia; and HAP which is a Michigan based Health Plan. In total, these insurers represent almost 26 million covered lives and enable access to this new treatment option for patients who may benefit from this therapy. Medtronic continues to work with other payers to expand coverage and provide this therapy to more patients.

"At Medtronic, we have a long-standing commitment to helping patients with medically refractory epilepsy through DBS, and we continue to explore other treatments and solutions along the epilepsy treatment pathway," said Mike Daly, vice president and general manager of the Brain Modulation business, which is part of the Restorative Therapies Group at Medtronic. "With the FDA approval, commercial launch, and policy updates from several health insurers, we are positioned to help more people than ever before. We are also initiating a 140 subject post-approval study where we will evaluate three-year safety and effectiveness outcomes at centers in the U.S. and Europe."

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 were the first 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.

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

Medtronic Intercept(TM) patient programmer

Medtronic Activa(TM) PC neurostimulator

Medtronic DBS Clinician Programmer

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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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 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] Epilepsy Foundation - Available at: https://www.epilepsy.com/learn/about-epilepsy-basics/who - Accessed February 11, 2019.

[2]Kwan P, Sander JW. The natural history of epilepsy: An epidemiological view. J Neurol Neurosurg Psychiatry. V.75(10):2004; 75: 1376-1381.

Contacts:

David T. Young
Public Relations
+1-774-284-2746

Ryan Weispfenning
Investor Relations
+1-763-505-4626