Medtronic News

Medtronic Launches First-of-Its-Kind Adaptive Deep Brain Stimulation (aDBS) Trial in Parkinson's Disease Patients

ADAPT-PD Global Study Designed to Demonstrate Safety & Efficacy of Automated Therapy Which Responds to Brain Signals in Parkinson's Disease Patients

DUBLIN, Jan. 14, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced the first enrollment in ADAPT-PD (**A**daptive **D**BS **A**lgorithm for **P**ersonalized **T**herapy in **P**arkinson's **D**isease), its trial evaluating the safety and efficacy of adaptive deep brain stimulation (aDBS) in patients with Parkinson's Disease (PD). Adaptive deep brain stimulation is an investigational feature of the Percept™ PC device that could be enabled if approved. The investigational feature used in this study allows for automated adjustment of brain stimulation to provide therapy to manage symptoms of Parkinson's disease based on a patient's clinical state.

The randomized study will take place across 12 study sites at leading Movement Disorders research centers in the United States, Europe, and Canada. An estimated 36 subjects will undergo a total evaluation period of 15 months. The primary endpoint of ADAPT-PD will compare standard continuous DBS (cDBS) to aDBS for hours of 'On' time without troublesome dyskinesias, a measure of treatment efficacy versus side effects, as reported by patient diary. Qualifying subjects in the study will receive cDBS at baseline followed by randomized evaluation of two different aDBS algorithms in a blinded manner.

Dr. Helen Bronte-Stewart, the John E. Cahill Family Professor in the Department of Neurology and Neurological Sciences at Stanford University and who is the North American principal investigator for the ADAPT-PD study, enrolled the first patient at the Stanford Movement Disorders Center. Dr. Bronte-Stewart and her collaborators previously laid the foundation for ADAPT-PD by performing the first closed loop deep brain stimulation studies in Parkinson's disease using an investigational prototype research-only system (Activa™ PC+S-Nexus D3). ADAPT-PD represents an evolutionary leap from these early studies in that sensing of brain signals and automated adjustment of stimulation are performed by using unlocked investigational features of the commercially available Percept PC DBS device, allowing patients in the study to be both treated and measured while outside the clinic.

According to the Parkinson's Foundation, more than 10 million people worldwide are living with Parkinson's disease and while similar, the progression of symptoms is often different from one patient to another due to the diversity of the disease. People with PD may experience tremor; slowness of movements (bradykinesia); limb rigidity; gait and balance challenges.

DBS is a well-established, safe and effective therapy for the treatment of motor symptoms in PD, including tremor (shaking); slowed movement (bradykinesia); and stiffness (rigidity) when medications aren't as effective as they used to be. Opportunities exist to improve the efficacy of DBS therapy. Current commercially-approved DBS systems deliver stimulation continuously (cDBS) and are adjusted manually within physician-defined limits to optimize therapy for the patient. In contrast, aDBS therapy may individualize and optimize PD therapy for the same motor symptoms as with cDBS by automatically adjusting stimulation within physician-defined limits, based on brain signals detected by the DBS system. ADAPT-PD will be using the Percept PC DBS system with investigational aDBS feature. While the aDBS feature is investigational and has not been approved for commercial use, the Percept PC device (cDBS) was approved by the FDA in June 2020. The Percept PC device

(cDBS) utilizes proprietary BrainSense™ technology making it the only DBS system with the ability to capture patient-specific brain signals. The sensing feature of the Percept PC system is intended for use in patients receiving DBS where chronically-recorded bioelectric data may provide useful, objective information regarding patient clinical status. Clinical benefits of brain sensing have not been established.

"Percept PC was developed with a significant amount of capabilities built into its system. We see this technology evolving to deliver even more value over time. The recently initiated ADAPT-PD is the first trial to gather clinical evidence to unlock those capabilities," said Mike Daly, vice president and general manager of the Brain Modulation business, which is reported as part of the Restorative Therapies Group at Medtronic. "Additionally, stimulation adjusted based on patient need, aDBS, could reduce total power output and possibly extend the life of the device."

Medtronic is a pioneer in DBS, developing a small, pacemaker-like device, placed under the skin of the chest or abdomen, to send electronic signals to an area in the brain that controls movement. DBS may help control movement symptoms associated with PD when medications are no longer as effective as they used to be. To date, more than 175,000 patients have been implanted with Medtronic DBS devices for management of Parkinson's symptoms and other conditions such as Essential Tremor, Epilepsy, Dystonia and OCD.

"aDBS technology will allow DBS to be responsive in real-time, communicating with the patient's brain, as needed - which could reduce the amount of programming burden on a clinician," added Professor Andrea Kühn, head of Movement Disorders and Neuromodulation, Charité University Hospital, Berlin. Professor Kühn is one of the leading scientists on electrophysiological markers for PD and designers of the ADAPT study; her team at the Charité, Universitätsmedizin Berlin implanted the first Percept PC DBS patient in the world.

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 175,000 Medtronic DBS devices have been implanted worldwide.

DBS therapy is currently approved in many locations around the world, including the U.S. and Europe, for the treatment of disabling motor symptoms of recent and longer-standing Parkinson's disease, essential tremor, and epilepsy. The therapy is also approved in the U.S. under Humanitarian Device Exemption (HDE) to treat chronic intractable primary dystonia and severe, treatment-resistant obsessive-compulsive disorder.

The FDA-approved indication for Parkinson's disease is as follows: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

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 90,000 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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