Medtronic News

FDA Approves Medtronic Deep Brain Stimulation for People with Parkinson's Disease with Recent Onset of Motor Complications

Approval Expands Population of Individuals Who May Benefit From the Proven Therapy

DUBLIN - February 17, 2016 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval of Medtronic Deep Brain Stimulation (DBS) Therapy for use in people with Parkinson's disease of at least four years duration and with recent onset of motor complications, or motor complications of longer-standing duration that are not adequately controlled with medication. In 2002, the FDA initially approved Medtronic DBS Therapy for use in patients with advanced Parkinson's disease. Medtronic DBS has demonstrated improvement in motor complications, quality of life, activities of daily living and reduction in medication usage in individuals with Parkinson's disease.1

Motor complications caused by the disease and/or as a side effect of levodopa result in great social and psychological disability.2 Interference with activities of daily living is often severe and the cost of treatment and care increases along with deterioration of quality of life for patients and their caregivers.2 Thirty-seven percent of people with Parkinson's retire earlier than those without the disease, retiring an average of six years earlier because of the disease.3 The economic impact of Parkinson's disease is at least $14.4 billion a year in the United States and it is estimated that the prevalence of the disease will more than double in the United States by the year 2040.4

"Strong clinical evidence demonstrates that, when compared to the best medical treatment alone, Medtronic DBS Therapy offers Parkinson's patients with recent onset of motor fluctuations and dyskinesias not adequately controlled with medication a higher likelihood of symptom improvement. Historically, the therapy has often not been considered until symptoms have had a significant impact on quality of life," said Mahlon DeLong, M.D., the W. P. Timmie professor of neurology at Emory University School of Medicine. "This decision by the FDA is significant in that Medtronic DBS Therapy may be considered before the symptoms and complications of disease become severe. Parkinson's patients should be referred to an experienced DBS multidisciplinary center for a comprehensive evaluation of possible Medtronic DBS therapy. For patients who are still functioning socially and able to work, this may translate into improved quality of life and an overall reduction of the burden of disease."

This recent approval by the FDA was based on data from the EARLYSTIM clinical study, published in the *New England Journal of Medicine* in 2013, which found that patients treated with Medtronic DBS Therapy and best medical therapy (BMT) reported a mean improvement of 26 percent in their disease-related quality of life at two years, compared to a one percent decline in patients treated with BMT alone.5 In a study of patients with longer-standing motor complications, DBS patients' quality of life improved 20 percent from baseline to six months compared to no improvement in the patients treated with BMT alone.1

"Parkinson's disease is progressive, and as a result a patient's quality of life will deteriorate over time. This approval is important because it expands the therapeutic window when patients can benefit from DBS," said Lothar Krinke, Ph.D., vice president and general manager of the Brain Modulation business, which is part of the Restorative Therapies Group at Medtronic. "Medtronic's goal is to advance medical care and deliver the best possible patient outcomes. DBS is proven to provide long-term benefits and it can now be used sooner in the care continuum, giving patients with recent onset motor complications another option to maintain or restore quality of life."

Impaired motor complications are associated with decreased quality of life, and the impact is similar for patients with recent onset or longer-standing motor complications.6 In the EARLYSTIM study, 85 percent of patients who received DBS along with BMT had a clinically meaningful improvement compared to only 36 percent in the BMT alone group over 24 months.5 Thirty percent of patients that remained on BMT alone got worse over 24 months compared to only two percent in the DBS group.5 The study also found a 61 percent improvement in levodopa-induced complications, including dyskinesias and motor

fluctuations, in participants receiving Medtronic DBS therapy at two years, compared to a 13 percent worsening in those only receiving BMT.5 Additionally, a long-term study of people with advanced Parkinson's disease who received DBS therapy show benefits at 10 years, despite potential surgical and device-related complications.7

About Parkinson's Disease

Parkinson's disease is a progressive, degenerative neurological movement disorder that affects approximately 1.5 million Americans.8 Although it typically develops after the age of 60, about 10-20 percent of people with the condition develop "young-onset" Parkinson's disease before reaching age 50.8 As Parkinson's disease progresses, it becomes increasingly disabling, making daily activities like bathing or dressing difficult or impossible. Parkinson's disease symptoms involve motor control, including shaking, slowness, stiffness and balance issues.

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 to reduce some of the most disabling motor symptoms associated with Parkinson's disease, including shaking, stiffness and movement difficulties. Medtronic's DBS systems are the first and only approved for full-body MRI scans under specific conditions. In most cases, DBS therapy is reversible and the system can be removed. Since 1997, more than 130,000 patients worldwide have benefited from Medtronic DBS Therapy.

The 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, recent and longer-standing Parkinson's disease and chronic intractable primary dystonia, the latter for which approval in the United States is under a Humanitarian Device Exemption (HDE). In Europe, Canada and Australia, DBS therapy is approved for the treatment of refractory epilepsy. DBS therapy is also approved for the treatment of severe, treatment-resistant obsessive- compulsive disorder in the European Union and Australia, and in the United States under an HDE.

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 85,000 people worldwide, serving physicians, hospitals and patients in approximately 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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