Medtronic News

Medtronic Receives FDA Approval to Launch Clinical Study for Implantable Tibial Neuromodulation Therapy for Bladder Incontinence

New Investigational Device Aims to Expand Access to Therapy for Patients with Incontinence; Underscores Medtronic's Leadership as Only Company to Offer Neuromodulation Options for Incontinence

DUBLIN, April 27, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced approval from the U.S. Food and Drug Administration (FDA) to proceed with an investigational device exemption (IDE) trial to evaluate its internally developed implantable tibial neuromodulation (TNM) device — a therapy designed to provide relief from symptoms of bladder incontinence. The TITAN 1 Feasibility Study is a prospective, multicenter, feasibility study to characterize the procedure for the implantable TNM device in subjects with bladder incontinence.

More than 37 million adults in the United States — almost one in six — suffer from overactive bladder (OAB)[1,2]. Of those, 4.5 million are candidates for an advanced therapy, yet only 5% receive treatment[3]. Implantable TNM aims to expand access to therapies for incontinence for more physicians and their patients.

For 25 years, Medtronic has pioneered sacral neuromodulation (SNM) therapy delivered by its implantable primary cell InterStim™ systems. Later the company enhanced its portfolio with the addition of PTNM delivered through the NURO™ system. In recognition that offering physicians and patients a choice between neuromodulation devices would help continue to expand access to the therapy, Medtronic further augmented its portfolio with the introduction of a rechargeable SNM device — InterStim™ Micro. Medtronic is the only company to offer a suite of neuromodulation options for the treatment of incontinence.

"Our goal is to stay at the forefront of therapy innovation, and we believe implantable TNM is an important part of the future of therapy for bladder incontinence," said Brett Wall, executive vice president and president of the Neuroscience Portfolio at Medtronic. "We remain completely committed to our sacral neuromodulation portfolio because this option is, and will continue to be, the best choice for many patients. Implantable TNM aims to be an extension of our belief that choice matters. No two patients are the same and their therapy should not be either."

Medtronic's combination of experience with implantable neuromodulation, its existing proprietary technology platforms and its proven effectiveness of PTNM therapy — as shown in the RESET study[4] — uniquely positions the company to develop a new TNM option for the market.

Implantable TNM stimulates the posterior tibial nerve near the ankle, transmitting electrical impulses that regulate neural activity of the bladder. Twenty patients from eight sites in the U.S. will receive a device and will be followed for 12 months. Enrollment is anticipated to begin in May 2021.

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.

[1]Stewart WF, et al. Prevalence and burden of overactive bladder inthe United States. World J Urol. 2003 May;20(6):327-336.

[2] United Nations, Department of Economic and Social Affairs, Population Division (2011). World Population Prospects: The 2010 Revision, CD-ROM Edition.

[3] Leede Research, "Views on OAB: A Study for the National Association of Continence."December 16, 2015.

[4] Kobashi K, Nitti V, Margolis E et al. A prospective study to evaluate efficacy using the NURO percutaneous neuromodulation system in drug naive patients with overactive bladder syndrome. Urology. 2019;131:77-82.

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