Medtronic News

Medtronic announces first patient implants of investigational implantable tibial neuromodulation therapy for bladder incontinence

TITAN 2 pivotal study to evaluate implantable tibial neuromodulation (TNM) device to help expand patient access to advanced therapy

DUBLIN, March 24, 2022 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced the first patient implants in the TITAN 2 pivotal study that will evaluate the safety and efficacy of Medtronic's investigational implantable tibial neuromodulation (TNM) device in people with overactive bladder (OAB). The minimally invasive technology stimulates the posterior tibial nerve near the ankle, transmitting electrical impulses that regulate neural activity of the bladder.

"Implantable TNM has the potential to offer relief to millions who suffer from bladder incontinence through a new approach that will provide greater convenience and more options for physicians and patients," said Una Lee, M.D., FPMRS, urology specialist at Virginia Mason Medical Center and national principal investigator for the TITAN 2 study. "The first patient implants in the Titan 2 study marks the beginning of what may be an important part of the future for better bladder control."

Implantable TNM aims to expand access to therapies for incontinence for more physicians and their patients. More than 37 million adults in the U.S. — almost one in six — suffer from OAB.[1,2] Of those, 4.5 million are candidates for an advanced therapy, yet only 5% receive treatment.[3] Medtronic currently offers percutaneous tibial neuromodulation (PTNM) therapy through its NURO™ system, but PTNM requires patients visit a clinic setting to receive therapy and return for repeat treatments. An implantable TNM device would reduce the burden on patients and physicians by delivering ongoing treatments without the need for additional clinic visits. Additionally, the procedure is less invasive than sacral neuromodulation, the current standard of care.

The TITAN 2 study is a prospective, multicenter, pivotal study to examine the safety and efficacy of the implantable TNM device in people with OAB. The study will include up to 130 patients from up to 30 sites in the U.S. The primary endpoint for the study is six months, and patients will be followed for 24 months.

Launched in April 2021, the TITAN 1 feasibility study characterized the procedure for the implantable TNM device in subjects with bladder incontinence. Upon successful completion of TITAN 2, Medtronic will prepare its submission to the U.S. Food and Drug Administration (FDA) for approval.

"Medtronic's decades of experience with implantable neuromodulation, existing proprietary technology platforms and the proven effectiveness of our PTNM[4] therapy uniquely positions us to bring implantable TNM to the market. We're confident this new option will truly meet the needs of physicians and patients," said Mira Sahney, president of the Pelvic Health business, which is part of the Neuroscience Portfolio at Medtronic. "TITAN 2 demonstrates our commitment to investing in the future and expanding access to advanced therapies for the treatment of incontinence."

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. Recognizing that offering a suite of device options to best fit a patient's lifestyle and treatment goals would help expand access to advanced therapy, Medtronic further augmented its portfolio with

the introduction of the smallest SNM device on the market – the rechargeable InterStim™ Micro – and, most recently, InterStim X™ — the next generation of its recharge-free SNM device, which provides more than 10 years of battery life without the need to recharge and up to 15 years under low energy settings.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

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 in the 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, et al. A Prospective Study to Evaluate Efficacy Using the NURO Percutaneous Tibial Neuromodulation System in Drug-Naïve Patients With Overactive Bladder Syndrome. Urology. 2019 Sep;131:77-82.

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