Medtronic News

Medtronic Begins Post-Market, Real-World Study of the InterStim™ Micro System

ELITE Study Designed to Confirm Long-Term Safety, Efficacy and Patient Benefit of Sacral Neuromodulation with the InterStim™ Micro System for Treatment of Overactive Bladder, Fecal Incontinence and Non-Obstructive Urinary Retention

DUBLIN, Aug. 20, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has begun recruitment of the prospective, multicenter, global, post-market study of the InterStim™ Micro system for sacral neuromodulation (SNM) therapy. Medtronic announced approval from the U.S. Food and Drug Administration for the InterStim Micro neurostimulator on August 3, 2020, and CE Mark on January 13, 2020.

“SNM therapy is already proven to be safe and effective, but we expect the ELITE study to definitively reinforce established SNM evidence in patients implanted with the new InterStim Micro system,” said Victor Nitti, M.D., the Shlomo Raz Chair in urology, professor of urology and obstetrics and gynecology, and chief and fellowship director of Female Pelvic Medicine and Reconstructive Surgery at the David Geffen School of Medicine at UCLA. “We hope the results of the study will encourage even more patients suffering from incontinence to pursue SNM therapy.”

More than 37 million adults in the United States — almost one in six — suffer from overactive bladder (OAB)[1,2] and nearly 18 million Americans — about one in 12 — have bowel incontinence.[3,4] Many sufferers limit their lives socially, professionally, and personally[5]; however, as many as 45% who suffer from symptoms do not seek treatment.[6]

The Evaluation of InterStim Micro System Performance and Safety (ELITE) study will enroll 160 subjects with overactive bladder (OAB), fecal incontinence (FI) and non-obstructive urinary retention (NOUR) — the most indications of any other study on the market — across 40 sites in the United States (and United States Territories), Europe, Australia and Canada. Objectives include patient reported outcomes, disease specific quality of life questionnaires, and symptom diaries. Patients will be followed for two years.

“By initiating ELITE, Medtronic reinforces its long-standing commitment to SNM therapy,” said Brooke Story, vice president and general manager of the Pelvic Health & Gastric Therapies business, which is part of the Restorative Therapies Group at Medtronic. “In partnership with physicians, we developed SNM therapy more than 25 years ago, and the InterStim system is the gold standard in the industry. Our SNM technology is backed by the only existing 5-year clinical data on the market for all SNM indications, and we expect the ELITE study will fortify the established evidence.”

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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[3] Whitehead WE, Borrud L, Goode PS, et al. Pelvic floor disorders network. Fecal incontinence in US adults: epidemiology and risk factors. Gastroenterology. 2009;137: 512-517.

[4] United States Quick Facts. United States Census Bureau Web site. Available at: https://www.census.gov/quickfacts/table/PST045215/00. Accessed July 19, 2016.

[5] Dmochowski RR, Newman DK. Impact of overactive bladder on women in the United States: results of a national survey. Current Medical Research and Opinion. 2007;23:65-76.

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

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