Medtronic News

Five-Year Data Demonstrate InterStim(TM) Therapy Offers Sustained Long-Term Efficacy and Quality of Life Improvements for Overactive Bladder Patients

The InterStim System is the Only Proven, Long-Term Sacral Neuromodulation Solution for Overactive Active Bladder

DUBLIN - July 17, 2017 - Medtronic plc (NYSE: MDT) today announced that the InterStim(TM) system, which provides sacral neuromodulation therapy, offers sustained long-term efficacy and quality of life improvements for overactive bladder (OAB) at five years.1 Results of the InSite study, which were published online in the *Journal of Urology*,1 found that 82 percent of patients had therapeutic success (defined as a greater than 50 percent improvement in symptoms) at five years and sustained quality of life improvements.

"Effective long-term bladder control is critical because OAB is a chronic condition that significantly impacts all aspects of a person's quality of life, including confidence, activities and intimacy," said Steven Siegel, M.D., primary investigator and director, Metro Urology Centers for Female Urology and Continence Care, Minneapolis, Minn. "Many struggle to find long-term relief and these results, which show the InterStim system offers sustained long-term efficacy, meaningful symptom reduction and quality of life improvements, offer new hope for those who suffer."

The prospective InSite study evaluated the efficacy and safety of the InterStim system at five-years in patients with bothersome OAB symptoms, who had failed or could not tolerate more conservative treatments, including urinary urge incontinence (UI) and/or urgency-frequency (UF). The five-year results include:1

- The overall therapeutic success rate was 82 percent using the completers analysis (subjects with data at baseline and each follow-up) and 67 percent using the modified completers analysis (subjects who either had a baseline and follow-up evaluation or withdrew early due to device-related reasons and are considered failures)
- Forty-five percent of patients with UI had complete continence
- UI patients had an average reduction of 2 leaks per day ($p<0.0001$) and UF patients had a mean reduction of 5.4 voids per day ($p<0.0001$)

In addition, patients experienced sustained quality of life improvements measured using the ICIQ-OABqol questionnaire ($p<0.0001$) that were three times greater than what is considered clinically significant

The InSite study demonstrated that the InterStim system was a safe option for OAB sufferers. The most common device-related adverse events were undesirable change in stimulation, implant site pain and ineffectiveness.1 The study reported only one serious device-related adverse event associated with the InterStim system.1 Implanting an InterStim system has risks similar to any surgical procedure.

"The InterStim system has been an important treatment option for 20 years and is the only sacral neuromodulation treatment with five-year clinical data demonstrating sustained, long-term efficacy for the treatment of both OAB and fecal incontinence," said Linnea Burman, vice president and general manager of the Pelvic Health & Gastric Therapies business, part of the Restorative Therapies Group at Medtronic. "These data should give physicians and patients confidence that relief and restored quality of life are possible and we hope this will help encourage the many still suffering from bothersome OAB symptoms to seek help."

About Overactive Bladder

The number of OAB patients is immense and increasing - more than 37 million Americans, or nearly 1 in 6 suffer - OAB is more common than diabetes or asthma.2,3,4,5 The condition significantly impacts quality of life, and can negatively affect social activities, exercise and cause disruptive nighttime voiding.6,7 Many sufferers are frustrated and embarrassed and limit their lives socially, professionally, and personally.8 However, 4.5 out of ten don't seek treatment and as many as seven in 10 stop

using medications within six months due to intolerable side effects or unsatisfying results.9,10,11

Evidence points to OAB being caused by a miscommunication between the bladder and brain.12 InterStim therapy uses neuromodulation, or gentle nerve stimulation, to normalize the brain-bladder communication pathway. InterStim is thought to restore bladder function by targeting the sacral nerves to help alleviate symptoms. Restore is defined as >=50 percent reduction in dysfunctional voiding symptoms from baseline.

About Medtronic InterStim Therapy for Bladder and Bowel Control

Medtronic is the first and leading provider of neuromodulation solutions for bladder and bowel control issues. Sacral neuromodulation therapy delivered by the InterStim system was first approved twenty years ago in 1997 and has helped more than 250,000 patients worldwide. For important safety information please visit www.medtronic.com/interstimsafety.

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 91,000 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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Contacts:

Lindsey Dickinson

Public Relations

+1-763-526-9452

Ryan Weispfenning
Investor Relations
+1-763-505-4626

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