Medtronic News

Prospective Data Demonstrates Effective Pain Relief and Improved Function Using Medtronic's Evolve(SM) Workflow with Spinal Cord Stimulation

To Assess the Potential of Non-Opioid Treatment Options for Chronic Pain, Study Evaluates Pain Relief, Patient Function and Satisfaction

DUBLIN and LAS VEGAS - May 7, 2019 - Medtronic plc (NYSE:MDT) today announced primary endpoint (3-month) results of the Vectors Post Market Clinical Study that demonstrated effective pain relief and improved function in patients with chronic intractable back and leg pain treated with spinal cord stimulation (SCS) utilizing the EvolveSM workflow*.1,2 Medtronic offers the Evolve workflow to help physicians balance high-dose (HD) and low-dose (LD) therapy settings on Medtronic SCS systems, including the Intellis(TM)platform. Results were presented at the American Society of Interventional Pain Physicians (ASIPP) annual meeting and found that patients experienced a statistically significant and clinically meaningful3 improvement with 69 percent of patients experiencing >= 50 percent improvement in overall pain and 70 percent achieving a personal activity goal at three months.1,2

"More and more clinicians are seeking long-term, non-opioid treatments for chronic pain, so it's important to understand how to best optimize SCS treatment with tools like the Evolve workflow," said John Hatheway, M.D., Northwest Pain Care of Spokane, Washington and primary investigator. "The potential for SCS to provide meaningful long-term improvements in quality of life, activities of daily living, and function is critical. It's encouraging that results from the Vectors study are showing effective pain relief and improved patient function."

Ninety percent of study subjects had a successful screening trial. One-hundred-three were then implanted with the device, and 98 patients completed the primary endpoint (3-month) visit. Data from the study demonstrated sustained pain relief, improved quality of life and decreased disability after device implant.1,2

- 69 percent of patients had at least a 50 percent improvement in overall pain
- 70 percent of patients achieved a personal activity goal
- 81 percent of patients were satisfied with their therapy
- 65 percent improved at least one disability category in the Oswestry Disability Index (ODI)

The prospective, single-arm, multicenter Vectors study was designed to provide evidence for the Evolve workflow by assessing the effectiveness and potential patient benefits of SCS while having access to both HD and LD stimulation modalities. SCS has traditionally used LD stimulation (40 Hz); however, HD stimulation (1000 Hz), the starting point for the Evolve Workflow, is becoming a more common starting frequency.4,5 At three months, 96 percent of patients remained on HD therapy alone.1,2

"Every patient is different, and to truly advance patient care we need clinical evidence that demonstrates significant benefits in pain relief and also looks beyond that to patient quality of life, function and satisfaction," said Marshall Stanton, M.D., senior vice president and president of Medtronic's Pain Therapies division, which is part of the Restorative Therapies Group. "Medtronic's goal is to help clinicians maximize the potential impact of SCS and give their patients the best possible long-term outcomes. We continue to invest in research, like the Vectors study, to build clinical evidence and understand how we can continue to strive for the best therapy options for each individual patient."

The Vectors study was conducted with Intellis, the world's smallest fully implantable spinal cord stimulator, with Medtronic's proprietary AdaptiveStim(TM) technology. The study will continue to follow patients through 6- and 12-month follow-up.

About Chronic Pain

At least 100 million American adults - more than the combined total affected by heart disease, cancer, and diabetes - are affected by chronic pain.6 Chronic pain can negatively impact all aspects of a person's life - relationships, work productivity and activities of daily living, yet it remains under-recognized and undertreated.7 It is estimated that the cost to treat chronic pain in the U.S., as well as related lost productivity, is as high as $635 billion annually.8

About Spinal Cord Stimulation

Neurostimulation has been proven to provide effective long-term pain relief and improve quality of life, and may be a non-drug treatment option for patients who do not get adequate pain relief from medication alone.9-13Medtronic neurostimulation therapy for chronic intractable pain uses a medical device placed under a patient's skin to deliver mild electrical impulses through a lead implanted in the epidural space to block pain signals from going to the brain. Spinal Cord Stimulation therapy may not be appropriate for everyone. Patients should discuss the potential risks and benefits of the therapy with a physician.

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 86,000 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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* A workflow is guidance only and physicians should use their medical judgment and product labeling to optimize therapy for individual patients, which may require discontinuation or modification of a workflow.

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