Medtronic News

Medtronic Enrolls First Patient In Pain Study to Assess Optimized Spinal Cord Stimulation Programming

As More Physicians Seek Non-Opioid Treatment Options, the Vectors Study Will Further Advance Understanding of New Approaches to Optimal Spinal Cord Stimulation Treatment

DUBLIN - January 9, 2018 - Medtronic plc (NYSE:MDT) today announced the first patient enrolled in the Vectors Post Market Clinical Study. The study will follow patients with chronic intractable pain who are undergoing spinal cord stimulation (SCS) treatment managed with the EvolveSM workflow*, which standardizes guidance that balances high-dose (HD) and low-dose (LD) therapy settings to help physicians optimize treatment. Evolve runs on Medtronic SCS systems including Intellis(TM), the world's smallest implantable SCS neurostimulator, which recently received U.S. Food and Drug Administration and CE Mark approval. The first patient was enrolled by The Center for Interventional Pain & Spine in Wilmington, Delaware.

"Our goal is to improve or restore function. Even with all of today's technological advances, chronic pain can be challenging to manage; this is further complicated by the opioid crisis," said Michael Fishman, M.D., from The Center for Interventional Pain & Spine. "Standard treatment guidance has the potential to help optimize pain relief, and the Vectors Post Market study will provide valuable data about the efficacy of high dose stimulation using standardized programming through the Evolve workflow."

The Vectors study is a prospective, multi-center, post-marketing study that will enroll up to 175 patients with chronic intractable pain of the low back and legs at up to 25 sites in the U.S. The study will assess SCS's long-term efficacy and impact on quality of life and was designed to provide evidence for the Evolve workflow by evaluating the effectiveness and potential patient benefits of having access to both HD and LD stimulation modalities. Patients will be followed for 12 months post implant.

"The Vectors study will generate meaningful data about the use of the Evolve workflow and will help further physicians' understanding of how to use this simple, versatile approach to enable effective, long-term pain relief with SCS," said John Hathaway, M.D., Northwest Pain Care of Spokane, Washington and primary investigator. "Knowing how to best use non-opioid treatment options - like the Intellis SCS platform - is more important than ever, and this data may help us expand our ability to help people struggling with chronic intractable pain."

The Intellis platform offers important patient benefits. Using Medtronic's proprietary Overdrive(TM) battery technology, the Intellis platform can be fully recharged in approximately one hour, addressing a common patient complaint about the burden of recharging their implant. Physicians also get new tools, including Snapshot(TM), a software platform that tracks activity, body positions and therapy usage. This empowers physicians with objective insights about patient outcomes, like mobility and progress.

"Medtronic is committed to advancing the treatment of people with intractable chronic pain. To maximize our impact, our goal is to expand the clinical understanding of optimal approaches to SCS treatment," said Marshall Stanton, M.D., senior vice president and president of Medtronic's Pain Therapies division, which is part of the Restorative Therapies Group. "Building on our 40-year legacy, the Vectors study will provide important evidence about how to best leverage both high dose and low dose stimulation with the Evolve workflow, which was designed to simplify patient management and standardize therapy for the best possible outcome. It's not just about pain relief, but about return to function."

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.1 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.2 Neurostimulation has been proven to provide

effective long-term pain relief and improve quality of life, in addition to being a treatment option for patients interested in trying a non-drug alternative.3-7

About Spinal Cord Stimulation

Medtronic 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. SCS is a non-opioid therapy that is clinically-proven and cost-effective for treating chronic pain. Multiple randomized controlled trials have demonstrated that SCS provides more effective pain relief than both re-operation and conventional medical management.3-5, 8

About Medtronic Pain Therapies

Medtronic has the broadest portfolio of pain therapies, which have been in use for over 40 years and have benefited hundreds of thousands of patients worldwide. Medtronic developed and leads the field of neuromodulation, the targeted and regulated delivery of electrical pulses and pharmaceuticals to specific sites in the nervous system, and continues to innovate and bring patient-centric advances, including new minimally invasive spine surgical technologies.

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 84,000 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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* 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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