Medtronic News

Medtronic Receives CE Mark for the World's Smallest Fully Implantable Spinal Cord Stimulator and Announces European Launch of the Intellis Platform

New Neurostimulation System Is a Non-Opioid Alternative for Chronic Pain and Offers Personalized Pain Relief and Advanced Activity Tracking

DUBLIN - November 6, 2017 - Medtronic plc (NYSE:MDT) today announced that it received CE (*Conformité Européenne*) Mark for the Intellis(TM) platform for both Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) as an aid in the management of certain types of chronic pain.* Intellis, the world's smallest fully implantable SCS neurostimulator, simplifies and improves the patient experience with improved battery performance that can power the EvolveSM workflow,** which standardizes guidance and balances high-dose (HD) and low-dose (LD) SCS therapy settings. The Intellis platform is managed on the Samsung Galaxy Tab S2 tablet interface and can record and track patient activity 24/7. Intellis is now available in Europe and the United States.

One in five adults in Western Europe suffers from chronic pain, a devastating condition with a costly personal and societal impact.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.1

Published studies have shown that when used by carefully selected patients with chronic pain, SCS may provide effective long-term pain relief, improved quality of life and pain-related disability, and may reduce the need for pain medications.2 Similarly, PNS may also provide back pain relief, improvement in back pain-related disability, and reduce the need for pain medications.3-4 The potential benefits of neurostimulation are critical given the public health issue of prescription pain medication abuse.5

Earlier intervention with SCS has been shown to improve treatment outcomes6 and SCS is widely reimbursed and recommended by European governments.7-9 Current European guidelines support the use of SCS; failed back surgery syndrome is the primary indication recommended by European governments.10

The first European patient received the Intellis system at the Pain Clinic of AZ Nikolaas Hospital in Sint-Niklaas, Belgium where Prof. Jean-Pierre Van Buyten is Chairman and the procedure was performed by Dr. Iris Smet.

"Chronic pain is a complex disease that is challenging to manage. The innovations behind the Intellis platform translate into meaningful patient benefits and ease of use for physicians, which represent important advantages over other neurostimulators," said Dr. Iris Smet from AZ Nikolaas. "I want to restore my patient's health and improve their quality of life; the innovation behind the Intellis platform allows me to achieve that and help a broad range of patients."

The Intellis platform can help optimize treatment and improve patient-physician communication by tracking and sharing daily activities, body positions and therapy usage and giving physicians an objective look at mobility and progress.

"Rather than rely on patient-reported data, the enhanced activity tracker of the Intellis platform provides real-time data that offers more visibility into quality of life changes," said Prof. Jean-Pierre Van Buyten of AZ Nikolaas. "Better understanding a patient's experience can lead to a more informed conversation that can help me maximize their pain relief and this information is easy to see and act on with the improved Samsung Galaxy tablet physician programmer."

"Medtronic's goal is to simplify treatment and improve the patient experience with personalized therapy that provides long-term pain relief and helps restore function," said Marshall Stanton, M.D., senior vice president and president of Medtronic's Pain Therapies division, which is part of the Restorative Therapies Group. "The launch of the Intellis platform is the culmination of 40 years of innovation and what makes Intellis such an important option is that it integrates leading-edge hardware with the Evolve

workflow for SCS to help optimize pain relief."

About the Intellis Platform

The Intellis platform addresses a common patient issue: battery recharging. With Medtronic's proprietary Overdrive(TM) battery technology, the Intellis battery can be fully recharged from empty to full in approximately one hour and physicians can now estimate recharge intervals based on therapy settings. Secure wireless Samsung Galaxy Tab S2 programmers for physicians enable faster delivery of evolving workflows and software upgrades on the Intellis platform. Intellis also includes both Medtronic's proprietary SureScan(TM) MRI technology for the broadest access available to MRI diagnostic imaging and simple eligibility determination, which allows MRI scans anywhere on the body under certain conditions for SCS patients, as well as AdaptiveStim(TM) technology for automatic adjustments to deliver the right therapy dose to the right location, as the pain target shifts based on body position.

About Spinal Cord Stimulation

Medtronic SCS therapy for chronic pain uses a small medical device called a neurostimulator placed under a patient's skin to deliver mild electrical impulses through a lead implanted in the epidural space, which act to block pain signals from going to the brain.

About Peripheral Nerve Stimulation

In Peripheral Nerve Stimulation, a small medical device called a neurostimulator sends mild electrical signals directly to the nerves under the skin near the area of pain, aiming to interrupt or modify the pain messages before they reach the brain.

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. Medtronic Pain Therapies are reversible, and patients start with a trial period to judge efficacy.

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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* The Intellis SCS neurostimulation system is indicated for SCS as an aid in the management of chronic, intractable pain of the trunk and/or limbs.

The Intellis PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the posterior trunk.

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

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