Medtronic News

Medtronic Enrolls First Patient in Clinical Study to Assess Pain Control and Oral Opioid Elimination with Targeted Drug Delivery

Study Will Further Advance Understanding of Effectiveness and Tolerability of the SynchroMed(TM) II Intrathecal Drug Delivery System in Patients Who Have Weaned off Oral Opioids

DUBLIN - January 17, 2019 - Medtronic plc (NYSE:MDT) today announced the first patient enrolled in the Embrace TDD (targeted drug delivery) clinical study that will evaluate the use of the SynchroMed(TM) II intrathecal drug delivery system ("Medtronic pain pump") as an alternative to oral opioids for patients with chronic intractable non-malignant primary back pain with or without leg pain. The Medtronic pain pump provides effective pain relief at a fraction of the oral dose with fewer side effects and may help reduce or eliminate the use of oral opioids.1-7 The Embrace TDD study will follow patients who wean completely from all oral opioids and have a successful intrathecal drug trial. The first patient was enrolled by John A. Hatheway, M.D., in Spokane, Wash.

Oral opioids are widely used to treat pain; however, there is limited evidence on the effectiveness and benefits of long-term oral opioid therapy.8 Given the current opioid epidemic and ongoing pain management crisis, there is a need to better understand solutions that effectively address chronic pain and support the elimination of oral opioids. There is evidence that oral opioid tapering and elimination may improve pain relief and allow for treatment with a lower effective dose of intrathecal medication compared to a combination of oral and intrathecal treatment.6 The Embrace TDD study was designed to further understand the impact of an opioid-free period prior to TDD treatment on patient outcomes.

"There are several strategies to approach weaning prior to or following TDD treatment. The Embrace TDD study is important because it will evaluate the impact of weaning patients completely off oral opioids before treating them with intrathecal therapy using the Medtronic pain pump," said John A. Hatheway, M.D., owner and provider, Northwest Pain Care, Spokane, Wash. "My goal is to provide patients with effective pain relief and help them eliminate long-term oral opioid use. Understanding the effect of being opioid free prior to TDD treatment may be clinically relevant as clinicians seek to optimize the use of long-term alternatives to oral opioids."

The Embrace TDD study is a prospective, multi-center, post-market study that will enroll approximately 100 patients with chronic intractable non-malignant primary back pain with or without leg pain at up to 15 sites in the U.S. Patients will wean from all oral opioids prior to initiating intrathecal therapy. The study will assess pain control and opioid-related side effects at six months following a route of delivery change to intrathecal preservative-free morphine sulfate. Patients taking a daily systemic opioid dose of <= 120 Morphine Milligram Equivalents (MME), who are candidates for TDD, are eligible. Patients will be followed for 12 months. More details can be found at ClinicalTrials.gov.

"As part of our commitment to helping address the opioid crisis, Medtronic is investing in clinical research and tools that can increase understanding of how to use proven alternative treatments, like TDD, for patients with uncontrolled chronic pain," said Charlie Covert, vice president and general manager, Targeted Drug Delivery, Medtronic Pain Therapies. "We hope the Embrace TDD study will provide valuable insights about how to best optimize use of the Medtronic pain pump and enable clinicians to help more patients with chronic pain, which has a significant personal and societal impact."

The Medtronic pain pump and catheter are implanted under the skin and deliver medication into the intrathecal

space, enabling clinicians to prescribe reduced doses compared to systemically delivered medications and tailor drug delivery to patient needs. Medtronic recently launched the Control WorkflowSM, an evidence-based approach for use with the Medtronic pain pump that helps physicians wean patients off oral opioids and assists them in identifying patients likely to have positive outcomes with the Medtronic pain pump. It was developed by clinicians and provides comprehensive guidance on therapy initiation, catheter placement, and dosing that could impact successful outcomes with the goal of sustained pain relief and functional improvement.1,6

About Chronic Pain

Chronic pain, which lasts more than three to six months, is a disabling condition that adversely affects wellbeing and can interfere with working, sleeping, and participating in physical activities, ultimately affecting quality of life. At least 100 million American adults - more than those affected by heart disease, cancer, and diabetes combined - are affected by chronic pain.9 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.10

About Medtronic Pain Therapies

Medtronic has more than a 40-year history of developing innovative medical devices that have been shown to alleviate pain in different disease states and has a broad portfolio of device-delivered therapies that are alternatives or adjuncts to oral opioids.3 Medtronic strives to be at the forefront of medical device innovation and to develop high-quality pain therapies that reduce pain and improve quality of life. While Medtronic pain therapies do not treat opioid addiction, we are committed to leveraging our capabilities and product portfolio in partnership with stakeholders - patients, providers, payers, regulators, elected officials, patient advocacy groups and employers - to address the unmet needs of pain patients and to support efforts to prevent opioid misuse due to chronic intractable pain.

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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