Medtronic News

Medtronic Launches the Control Workflow(SM) to Help Eliminate Oral Opioids and Provide Effective Pain Relief

(GLOBE NEWSWIRE via COMTEX) --For Use with SynchroMed(TM) II Intrathecal Drug Delivery System, the Control WorkflowAims to Effectively Address Chronic Pain Without the Use of Oral Opioids

DUBLIN - October 16, 2018 - Medtronic plc (NYSE: MDT) today announced the U.S. launch of the Control WorkflowSM, an evidence-based approach for use with the SynchroMed(TM) II intrathecal drug delivery system ("Medtronic pain pump") that helps physicians wean patients off oral opioids and treat chronic intractable pain. The Medtronic pain pump provides effective pain relief at a fraction of the oral dose with fewer side effects and has been shown to reduce or eliminate the use of oral opioids. 1-7 Prior to the Control Workflow, a retrospective claims analysis (n=389) found that 51 percent of chronic non-malignant pain patients eliminated the use of oral opioids after one year on the pump.5

Given the current opioid epidemic and ongoing pain management crisis, there is a need for solutions that effectively address chronic pain. Many people use oral opioids to treat pain; however, there is limited evidence on the effectiveness and benefits of long-term oral opioid therapy.8 The Control Workflow in combination with the Medtronic pain pump encourages oral opioid elimination and can be used as an alternative to long-term oral opioid therapy for appropriate patients.

"The Control Workflow assists me in identifying appropriate patients who could benefit from targeted drug delivery using the Medtronic pain pump, which is especially important with the current opioid epidemic in the United States," said John A. Hatheway, M.D., owner and provider, Northwest Pain Care, Spokane, Wash. "The workflow is especially helpful for patients who may be on high doses or cannot tolerate systemic opioids, or for those who are not finding pain relief with systemic opioid therapy. By placing the medication at the source of the pain, we can often provide better pain relief with fewer side effects at a fraction of the oral dose."

The Control Workflow includes oral opioid weaning considerations that can be tailored to individual patients and assists physicians in identifying patients likely to have positive outcomes with the Medtronic pain pump. It supports oral opioid tapering and drug holidays, allowing for treatment with the lowest effective dose of intrathecal medication, which may improve pain relief compared to a combination of oral and intrathecal treatment.6 This evidence-based approach 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

"There is a significant unmet need in chronic pain and device-delivered options are underutilized for appropriate patients, so we continue to innovate to maximize the value of proven treatments," said Charlie Covert, vice president and general manager of the Targeted Drug Delivery business, part of the Restorative Therapies Group at Medtronic. "We rolled out the Control Workflow to help simplify targeted drug delivery therapy, support oral opioid weaning, and offer more patients an effective alternative for pain relief. This is an important part of our commitment to help address the opioid epidemic and pain management crises. We will continue to partner with stakeholders to provide clinical guidance that helps physicians understand when to consider device-delivered treatments."

Many patients take progressively higher doses of oral opioids without improvement in pain control, function, and quality of life.8 It is suspected the chronic use of oral opioids may treat end-of-dose withdrawal rather than underlying pain, and patients frequently report that their opioid doses merely "take the edge off" their pain.9

Using the Control Workflowwith the Medtronic pain pump gives some chronic pain patients another option that may prove more effective than other therapies. These patients include those taking high dose oral opioids with low efficacy or those who can't tolerate oral opioids due to the side effects, such as constipation, drowsiness, or changes in cognition.

Targeted Drug Delivery, an Alternative to Oral Opioids

Oral opioid misuse is a significant issue, and it's more important than ever for patients suffering from chronic pain to have access to proven alternatives. Targeted drug delivery (TDD) may enable systemic opioid reduction or elimination and may be considered as an alternative to oral treatment for chronic pain.3 In a single-center, retrospective chart review (n=99) of patients with chronic non-malignant pain who agreed to transition from systemic opioids to TDD with the goal of eliminating systemic opioids, 84 percent were able to eliminate opioid therapy within one year.11

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.10 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.12

About SynchroMedII Intrathecal Drug Delivery System

The Medtronic SynchroMed II 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. Patients with chronic, intractable pain who have not had success with other treatment options or have experienced intolerable side effects with oral medications are candidates for the Medtronic pain pump.

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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