Medtronic News

FDA Approves New SynchroMed(TM) II myPTM(TM) Personal Therapy Manager That Enables Patients to Alleviate Unpredictable Pain

(GLOBE NEWSWIRE via COMTEX) --myPTM Allows Patients to Personalize Their Treatment by Delivering On-Demand Boluses, or Drug Doses, Within Therapeutic Limits Set by Their Physician

DUBLIN - October 24, 2018 - Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) approval of the new SynchroMed(TM)II myPTM(TM) Personal Therapy Manager for patients with chronic pain. This device enables patients to alleviate their unpredictable pain by delivering on-demand boluses, or drug doses, within therapeutic limits set by their physician.

myPTMworks with the SynchroMedII Intrathecal Drug Delivery system, also known as a Medtronic pain pump, which delivers medication directly to the fluid around the spinal cord to relieve chronic pain in appropriate patients. The Medtronic pain pump, an implantable drug pump, provides long-term pain relief at lower doses and with fewer side effects compared to oral pain medications and may allow some patients to eliminate the use of systemic opioids.1, 3, 4, 8, 9 Personalization of the therapy gives patients the ability to alleviate unpredictable pain and may further reduce the need for oral opioids.8

"Pain is very personal and can be unpredictable. myPTM is a simple, easy-to-use device that allows my patients to personalize their treatment based on their day-to-day needs," said John A. Hatheway, M.D., owner and provider at Northwest Pain Care in Spokane, Wash. "Enabling patients to adjust their treatment provides them with some independence to control their pain and gives me confidence knowing that they are getting pain relief without oral opioids. The Medtronic pain pump and myPTM are powerful tools to safely treat chronic pain including intractable cancer pain."

myPTM is an easy-to-use application on a touchscreen Samsung J3 smart device that is customized to empower patients to manage their pain. Healthcare providers can set daily therapeutic doses and allow for on-demand bolusing, or drug delivery, within pre-established limits. myPTM features clear bolus delivery, access to therapy details, and lockout alerts if patient demand exceeds prescribed limits. Physicians also have access to reports that provide insights needed to track progress and collaborate on therapy goals with their patients.

"Samsung and Medtronic have partnered to offer an innovative solution for patients with chronic pain," said Dr. David Rhew, chief medical officer, vice president and general manager for Enterprise (B2B) Healthcare, Samsung Electronics America. "The ability to directly manage one's medical condition from a smartphone device is ground breaking and changes the way we think about the personalization of care."

"We are striving to simplify targeted drug delivery therapy to make it more accessible. The Control WorkflowSM and Clinician Programmer provide physicians with tools to effectively administer the therapy, and the myPTM provides customized pain relief options for patients," said Charlie Covert, vice president and general manager of the Targeted Drug Delivery business, part of the Restorative Therapies Group at Medtronic. "As the opioid crisis continues, we are inspired by the Medtronic Mission to continue to innovate and expand access to care for patients who may benefit from our therapies, which have the potential to eliminate the need for oral opioids."

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 systemic opioids within one year.4

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.5 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.6

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.7 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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