Medtronic News

FDA Approves Innovative Clinician Programmer for the Medtronic SynchroMed II Intrathecal Drug Delivery System for Chronic Pain and Severe Spasticity

SynchroMed(TM) II for Chronic Pain Is an Alternative to Systemic Opioids for Many Patients

DUBLIN - January 10, 2018 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval of a new clinician programmer for use with the SynchroMed(TM)II Intrathecal Drug Delivery system, an implantable pump that provides targeted drug delivery for chronic pain and severe spasticity. The SynchroMed II pump delivers medication directly to the fluid around the spinal cord, which provides relief at lower doses compared to oral medications in appropriate patients with chronic pain1 or severe spasticity.2 The new SynchroMedII clinician programmer was designed to simplify therapy management by providing clinicians with visual tools and intuitive workflows and will soon be available in the U.S.

"With the ongoing opioid crisis, the ability to reduce the use of systemic opioids and effectively manage my patients' pain with the SynchroMed II pump system is more important than ever," said Joshua Wellington, M.D., Indiana University Health. "The new SynchroMed II clinician programmer helps simplify therapy management, enabling me to focus on providing my patients with pain relief through intrathecal delivery of medications so that systemic opioids are reduced or eliminated entirely."

The SynchroMed II clinician programmer is an application that runs on a tablet that includes a vibrant screen display and simple, guided workflows. The programmer features visual enhancements such as side-by-side comparison of therapy changes and flex dosing graphics. The clinician programmer communicates wirelessly to the SynchroMed II pump and auto-calculations help ensure accuracy and improve programming confidence. Medtronic also recently secured FDA approval and implemented four design changes to improve the design and performance of the SynchroMed II Pump.

"Our new clinician programmer follows a series of recent SynchroMed II Pump design changes and was developed with patient safety in mind; our goal was to make it intuitive and simple for clinicians to confidently tailor treatments to best meet patients' needs," said Charlie Covert, vice president and general manager, Targeted Drug Delivery, Medtronic Pain Therapies. "The ability to assist with decreasing the need for systemic opioids is critical, and Medtronic is committed to improving the lives of patients with chronic pain and severe spasticity through continuous innovation and therapy advancements."

Targeted Drug Delivery, An Alternative to Oral Opioids

Systemic opioid abuse is a significant issue. Targeted drug delivery will help allow for systemic opioid reduction or elimination and may be considered as an alternative to oral treatment for chronic pain.3 Intrathecal drug delivery has been demonstrated to provide long-term pain reduction.1

About Chronic Pain and Severe Spasticity

Chronic pain, which lasts more than three to six months, is a disabling condition that adversely affects wellbeing and can interfere with working, sleeping, participating in physical activities and enjoying life. At least 100 million American adults - more than the total affected by heart disease, cancer, and diabetes combined - are affected by chronic pain.4 People suffering from severe spasticity have tight, stiff muscles that make it difficult to move or control their arms, legs, or body, which can make everyday life exhausting and difficult.

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 or severe spasticity who have not had success with other treatment options or have experienced intolerable side effects with oral medications are candidates for SynchroMedII. The system is also

full-body MRI conditional under conditions specified in the product labeling. More than 375,000 patients worldwide have received therapy from Medtronic drug infusion systems since they were introduced over 30 years ago.

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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References

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