OCT 10, 2023

Medtronic receives FDA approval for SynchroMed™ III intrathecal drug delivery system for chronic pain, cancer pain, and severe spasticity

Medtronic, a global leader in healthcare technology, today announced U.S. Food and Drug Administration (FDA) approval of its next-generation SynchroMed™ III intrathecal drug delivery system for patients with chronic pain, cancer pain, and severe spasticity. SynchroMed III is a targeted drug delivery (TDD) platform that alleviates symptoms by delivering medication directly to the fluid surrounding the spinal cord. SynchroMed III is an upgraded system compared to the SynchroMed™ II system, featuring a new "refill only" physician workflow for more efficient programming, improved electronics with firmware capable of being updated after implant, and additional protections for patient data through enhanced cybersecurity. The system also carries forward several mid-generation durable design enhancements from the SynchroMed II pump which have contributed to the long-term safety and reliability of the device.[1]

TDD therapy is a safe, proven, and effective way to manage chronic pain, cancer pain or severe spasticity with greater efficacy, fewer side effects, and a high degree of clinician control as compared to systemic medication.[2,3,4,5,6,7,8] The system delivers medication directly to the fluid surrounding the spinal cord via a catheter connected to a small, battery-powered programmable pump. Patients with the SynchroMed III system will continue to have access to diagnostic imaging through industry-leading 1.5T and 3T full-body MRI conditionality.[9]

"Targeted drug delivery is a critically important therapy for the management of chronic pain, cancer pain or severe spasticity when oral medications are ineffective or cause intolerable side effects," said Dr. Chris Beuer, M.D., the director of pain management at Christian Hospital in St. Louis, Mo. "Systemic opioids bring significant risks, so I am pleased to be able to offer targeted drug delivery to my

patients as a safe and effective alternative. I'm also excited about the new refill-only workflow capabilities of the SynchroMed III system which will enable more efficient programming within my practice."

The SynchroMed III system can be used with the Control Workflow™, which is designed to help eliminate the use of systemic opioids by certain patients. Control Workflow is a framework that can be tailored to individual patients and assists physicians in identifying patients likely to have positive outcomes. 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.[2,10] 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.

"Medtronic has offered targeted drug delivery therapy for over 30 years, and we continue to further enhance this technology," said David Carr, vice president and general manager, Pain Interventions within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "The SynchroMed III system brings forward several important developments and represents another step forward in our commitment to delivering solutions that alleviate pain and improve lives through innovative medical technology."

The SynchroMed III system will be commercially available later this calendar year.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com, and follow @Medtronic on Twitter and LinkedIn.

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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[1] 2022 Product Performance Report

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[7] Meythaler JM, DeVivo MJ, Hadley M. Prospective study on the use of bolus intrathecal baclofen for spastic hypertonia due to acquired brain injury. Arch Phys Med Rehabil. 1996;77(5):461-466.

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[9] Under specific conditions for 1.5 T and 3.0 T MRI scans. Refer to product labeling.

[10] Grider JS, Harned ME, Etscheidt MA. Patient selection and outcomes using a low-dose intrathecal opioid trialing method for chronic nonmalignant pain. Pain Physician. 2011 Jul-Aug;14(4):343-51

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