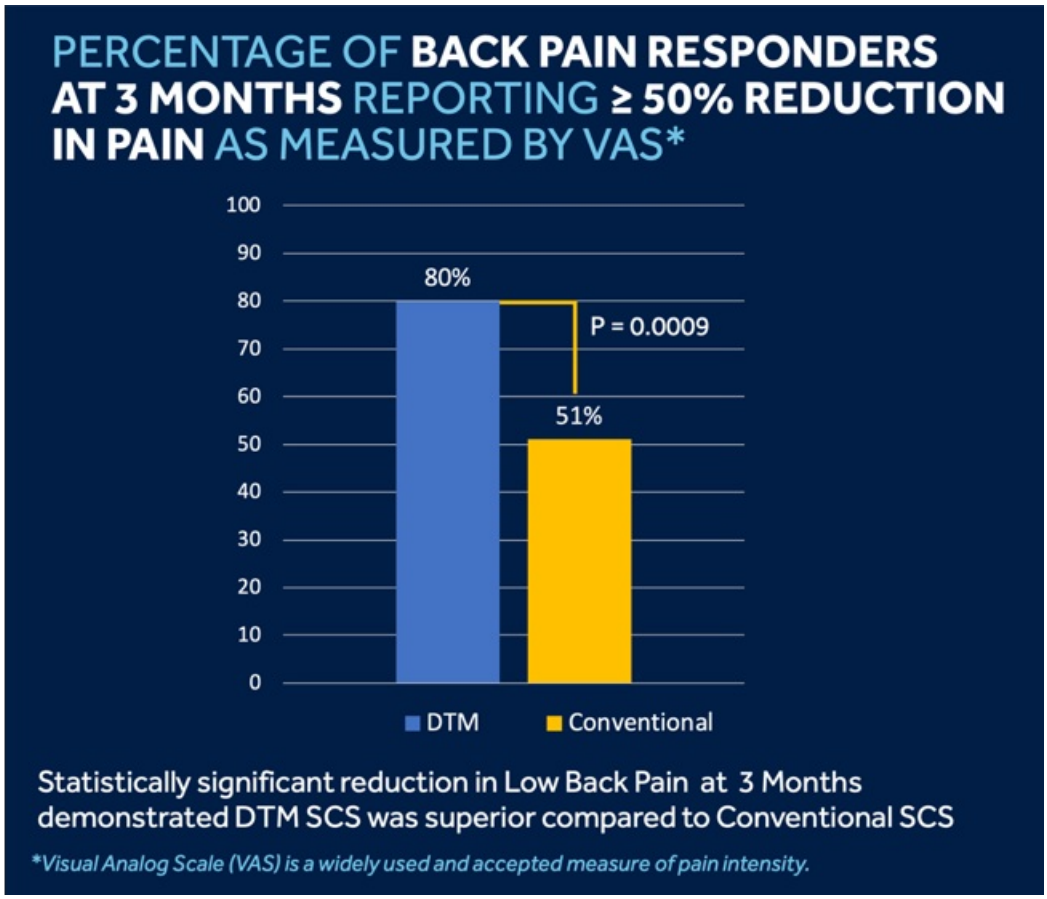
Medtronic News

DTM™ Spinal Cord Stimulation Using the Medtronic Intellis™ Platform Shows Superior Back Pain Relief Compared to Conventional SCS Therapy in an RCT

At Three-Months, 80% of Patients Treated with DTM SCS Reported Back Pain Relief of at Least 50%; 63% Reported Profound Back Pain Relief of 80% or Greater1

DUBLIN, Jan. 21, 2020 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced three-month results from a large, multicenter randomized controlled trial (RCT) showing statistically significant (p=0.0009) and superior back pain relief with Differential Target Multiplexed (DTM™) Spinal Cord Stimulation (SCS) compared to conventional SCS. Both arms used the Medtronic Intellis™ platform. Three-month results showed 80% of patients with chronic back pain treated with DTM reported at least 50% pain relief, compared with 51% of patients treated with conventional SCS, as measured by the Visual Analog Scale (VAS), a widely used and accepted measure for pain intensity.1 Fifty-percent pain relief, as measured by VAS, is a recognized industry standard to define minimum therapy success.



The RCT demonstrated profound pain relief and significant reductions in back and leg pain with DTM. Sixty-three percent patients with back pain treated with DTM reported profound pain relief of 80% or greater compared to 26% treated with conventional SCS. In aggregate, patients treated with DTM reported an average of 74% reduction in back pain compared to 46% with conventional SCS at three months.1 Similarly, improvements were observed with DTM for leg pain with a mean reduction of 72% compared to 59% with conventional SCS.1

The RCT results reported are from 94 implanted SCS patients who were randomized to either the treatment or control arm and followed over the course of three months. With these results the study met its primary endpoint of noninferiority compared with conventional SCS, and a pre-specified secondary statistical test for superiority showing the difference between DTM and conventional SCS as highly significant. The study will continue to follow patients through 12 months post implant.

Medtronic acquired DTM therapy as part of its acquisition of Stimgenics announced in early January. DTM therapy, which was proven through the RCT only on the Medtronic Intellis platform, is a new and unique programming option available to treat patients with chronic pain that is based on years of preclinical research.3,7

“DTM therapy is the first tailored SCS approach intentionally developed from a novel scientific concept and demonstrated in an RCT. The study demonstrates that DTM therapy provides superior efficacy for patients with chronic back pain compared to conventional stimulation,” said Matt Thomas, vice president and general manager of the Stim and Early Interventions business,

which is part of the Restorative Therapies Group at Medtronic. “Combined with Intellis, patients can access superior outcomes as demonstrated in the RCT on an unrivaled stimulation platform.”

The DTM waveform may engage a novel mechanism that modulates both neurons and glial cells, expanding the understanding of SCS mechanisms of action. Glial cells outnumber neurons in the spinal cord by 12:1 and their role in pain have been explored in research for more than 20 years.2-4

DTM has been studied in animal models, showing statistically significant reversal of pain behaviors compared to either low frequency or high frequency alone.6,7 In addition, preclinical studies investigating the genome of nerve-injured animals suggests that the DTM waveform has a greater impact in the neural-glial interaction than other frequencies. Basic science research is further expanding our understanding of SCS mechanisms of action. Glial cells are no longer thought to be only “glue” in the brain and spinal cord but active contributors to neural processing and various disease states including chronic pain.8

Results from the RCT are being presented at the North American Neuromodulation Society (NANS) annual meeting Jan. 23-26, 2020 in Las Vegas and can also be found on the Medtronic website.

Analyst and Investor Briefing

Medtronic will host a webcast on Friday, Jan. 24, 2020 from 8:30 a.m. to 9:30 a.m. Pacific Standard Time from the NANS annual meeting in Las Vegas. The webcast will feature remarks from the Medtronic Restorative Therapies Group management team. The live audio webcast can be accessed by clicking on the Investor Events link on the Medtronic Investor Relations website on Jan. 24. Within 24 hours of the webcast, a replay will be available on the same page. This event is not part of the official NANS 2020 program.

About the IntellisTM Platform

The Intellis platform offers the world’s smallest implantable neurostimulator. It is powered by proprietary Overdrive™ battery technology and was designed to overcome limitations with other SCS systems, optimized for a wide range of energy demands and provides effective long-term pain relief for patients. The neurostimulator also features SureScan™ MRI, allowing access to MRI anywhere in the body under certain conditions, and AdaptiveStim™ technology, which automatically adjusts stimulation based on the patient’s needs and preferences in different body positions to ensure the patient receives the right dose of stimulation at the right location.

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.9 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 90,000 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.

-end-

References

1. Fishman M, Cordner H, Justiz R et al. Randomized Controlled Clinical Trial to Study the Effects of DTM-SCS in Treating Intractable Chronic Low Back Pain: 3 Month Results. Presentation at NANS 2020, Las Vegas, Nevada.
2. Milligan ED, Watkins LR. Pathological and protective roles of glia in chronic pain. Nat Rev Neurosci. 2009 Jan;10(1):23-36.
3. Vallejo R, Tilley DM, Vogel L, Benyamin R. The role of glia and the immune system in the development and maintenance of neuropathic pain. Pain Pract. 2010 May-Jun;10(3):167-84.
4. De Leo JA, Tawfik VL, LaCroix-Fralish ML. The tetrapartite synapse: Path to CNS centralization and chronic pain. Pain. 2006; 122:17-21.
5. Ruiz-Sauri A., Orduña-Valls J.M., Blasco-Serra A. et al. Glia to neuron ratio in the posterior aspect of the human spinal cord at thoracic segments relevant to spinal cord stimulation. *Journal of Anatomy*, vol. 235, no. 5, 2019, pp. 997-1006.
6. Cedeno D.L., Cass C.L., Kelley C.A., et al. Pre-clinical comparison of differential-target multiplexed scstm with low and high rate SCS. Neuromodulation 2019 22:3 (E185-)
7. Cedeno D.L., Kelley C.A., Cass C.L., et al. Pre-clinical Comparison of Differential-Target Multiplexed SCS with Low and High Rate SCS. Presentation at ASRA 2018. San Antonio, Texas.
8. Allen NJ, Barres BA. Neuroscience: Glia - more than just brain glue. Nature. 2009 Feb 5;457(7230):675-7.
9. Deer T. *Atlas of implantable therapies for pain management.* New York, NY: Springer Science and Business Media, LLC; 2011.

Michelle Claypool

Public Relations

+1-763-526-9452

Ryan Weispfenning

Investor Relations

+1-763-505-4626

---

https://news.medtronic.com/2020-01-21-DTM-TM-Spinal-Cord-Stimulation-Using-the-Medtronic-Intellis-TM-Platform-Shows-Superior-Back-Pain-Relief-Compared-to-Conventional-SCS-Therapy-in-an-RCT