Medtronic News

Medtronic Initiates U.S. Trial to Evaluate the Use of Subcutaneous Peripheral Nerve Stimulation for Chronic Back Pain

MINNEAPOLIS - April 11, 2013 - Medtronic, Inc. (NYSE: MDT) today announced the first patient enrollments in the SubQStim II pivotal clinical trial to pursue U.S. Food and Drug Administration (FDA) approval of peripheral nerve stimulation (PNS), also known as subcutaneous nerve stimulation (SQS), for the reduction of chronic, intractable post-surgical back pain.

PNS involves an implant of electrical leads just under the skin of the lower back. These leads are connected to a stimulator which delivers mild electrical impulses to the nerves, interrupting pain signals traveling through the nervous system to the brain. Medtronic received CE (*Conformité Européenne*) Mark for the first 16-electrode, fully implantable system for the percutaneous delivery of PNS in the management of chronic back pain in May 2011. PNS using a fully implantable system is not currently approved by the U.S. Food and Drug Administration for use in the United States.

The SubQStim II pivotal study is a randomized, controlled, blinded, parallel arm, multicenter trial to assess the safety and efficacy of PNS for chronic, intractable post-surgical back pain. The study will recruit up to 323 people at 30 U.S. centers who will receive PNS using a Medtronic neurostimulation system. Subjects will be randomized to a treatment or control group for the first three months and will continue to participate in open label follow-up for up to five years.

"The SubQStim II pivotal study will provide new information about subcutaneous nerve stimulation as a potentially valuable treatment option for U.S. patients with chronic, intractable back pain who have found insufficient relief with other treatment options," said the study's coordinating investigator, George Mandybur, M.D., Associate Professor and Director Stereotactic and Functional Neurosurgery at the University of Cincinnati and a neurosurgeon with the Mayfield Clinic.

The first enrollments were performed by principal investigators Yeshvant Navalgund, M.D., of DNA Advanced Pain Treatment Center in Greensburg, Pennsylvania, and D. Joseph Meyer, M.D., Ph.D., of Columbia Interventional Pain Center in Columbia, Missouri.

"Study findings will provide an unprecedented understanding of how leads placed in the subcutaneous tissue layer work with neurostimulation devices to help patients manage their chronic back pain," said Dr. Navalgund.

The SubQStim II pivotal study is the latest in a series of clinical trials sponsored by Medtronic to generate a comprehensive portfolio of evidence demonstrating the clinical and economic value of its neurostimulation systems for the management of chronic pain. Medtronic recently initiated the SubQStim I post-market study in Europe, Israel, Australia and Canada to evaluate the effectiveness of PNS plus optimal medical management (OMM) for low back pain, compared to OMM alone in patients with Failed Back Surgery Syndrome (FBSS). In January, the company announced the beginning of PROMISE, a Prospective, Randomized Study of Multicolumn Implantable Lead Stimulation for Predominant Low Back Pain. PROMISE is the first-ever, large-scale study comparing the effectiveness of Medtronic neurostimulation therapy with Specify® 5-6-5 multicolumn surgical leads plus OMM, to OMM alone in patients with FBSS and predominant low back pain.

"Medtronic remains committed to investing in research to demonstrate the clinical and economic value of our industry-leading neurostimulation technology and ensure our therapies are available to those who may benefit,"

said Julie Foster, general manager and vice president, Pain Stimulation and Targeted Drug Delivery in the Neuromodulation business of Medtronic, Inc. "Chronic back pain affects a significant number of adults in the U.S., and if the SubQStim II pivotal trial results are positive, we plan to pursue FDA approval to make this potential treatment option available to patients who may benefit."

More information about Medtronic's SubQStim studies, including enrollment information, can be obtained at http://clinicaltrials.gov/ct2/results?term=subqstim. Patient information on approved Medtronic neurostimulation pain therapies is available at www.tamethepain.com or 1-888-430-PAIN (7426).

About Chronic Back Pain

It is estimated that 100 million U.S. adults live with chronic pain.[1] Back pain is the most prevalent type of chronic pain, affecting approximately 10 percent of the U.S. population.[2]Many patients suffering from chronic pain following spine surgery receive oral medications and other therapy, but clinical experience finds many of these patients fail to obtain adequate relief and will require additional interventions.[3]

Medtronic's Leadership in Neuromodulation

Medtronic developed and leads the field of neuromodulation, the targeted and regulated delivery of electrical pulses and pharmaceuticals to specific sites in the nervous system. The company's Neuromodulation business includes implantable neurostimulation and targeted drug delivery systems for the management of chronic pain, common movement disorders, spasticity and urologic and gastrointestinal disorders.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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 Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research; Consensus Report, Institute of Medicine (IOM), June 2011. Page 1. Retrieved Feb. 19, 2013, from: http://www.nap.edu/openbook.php?record_id=13172&page=1.

2Hardt J, Jacobsen C, Goldberg J, Nickel R, Buchwald D.: Prevalence of chronic pain in a representative sample in the United States. *Pain Medicine* 2008; 9:7: 0nstitute of Medicine (IOM), s are estimated tople in the United States. sequent implants depending on levell ulation to area803-812.

3Chan C, Peng P. Review Article: Failed Back Surgery Syndrome. *Pain Medicine* 2011; 12: 577-606.

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