Medtronic Initiates Landmark Study of Neurostimulation Therapy for Failed Back Surgery Syndrome

The Associated Press

First Patients Treated in Global Clinical Trial Evaluating Impact of Therapy on Predominant Low Back Pain

MINNEAPOLIS - January 28, 2013 - Medtronic, Inc. (NYSE: MDT) today announced the start of PROMISE, a Prospective, Randomized Study of Multicolumn Implantable Lead Stimulation for Predominant Low Back Pain. This is the first-ever, large-scale study comparing the effectiveness of Medtronic neurostimulation therapy with Specify® 5-6-5 multicolumn surgical leads plus optimal medical management (OMM) to the administration of OMM alone in patients with failed back surgery syndrome (FBSS) and predominant low back pain.

"Chronic pain is a clinically challenging and often debilitating condition for which oral medications may provide insufficient relief," said Bart Edmiston, M.D., principal investigator for the PROMISE study at The Neuroscience Center in Ocean Springs, Mississippi, which enrolled the study's first patient on January 8. "The PROMISE study will add to the growing body of evidence supporting Medtronic neurostimulation therapy, a well-established therapeutic approach, for the patients worldwide who continue to experience low back pain following back surgery."

It is estimated that more than 100 million U.S. adults1 and one in five European adults2 live with chronic pain. Back pain is the most prevalent type of chronic pain, affecting approximately 10 percent of the U.S. population alone.3 FBSS is defined as persistent or recurring pain in the back or legs following one or more spine surgeries. The majority of FBSS patients receive physical rehabilitation and/or oral medications to help manage their pain, but studies and clinical experience find that many of these patients will not sufficiently improve and will require additional interventions.4

Medtronic neurostimulation therapy (also known as spinal cord stimulation, or SCS) is a widely established treatment option for chronic back and/or leg pain that has been used to treat more than 250,000 people worldwide. It uses a medical device to deliver mild electrical impulses to the spinal cord to block pain signals from reaching the brain.

PROMISE is a prospective, randomized, open-label, parallel-group, clinical study enrolling up to 300 individuals suffering from predominant chronic low back pain due to FBSS at 30 centers in the United States , Canada and Europe (Belgium, France, Germany, Spain, The Netherlands and The United Kingdom). It is the first

large-scale, randomized, controlled clinical trial designed to assess the value of SCS for predominant low back pain with leg pain using a surgical lead, in contrast to previous studies of this technology, which have focused on predominant leg pain.

"Spinal cord stimulation has become an increasingly valued treatment approach in chronic pain, and we look forward to participating in the latest study," said Philippe Rigoard, M.D., the study's global principal investigator, who started enrolling patients January 14 at Poitiers University Hospital in Poitiers, France. "If the PROMISE results are positive, they will provide critically needed relief for those patients suffering from chronic low back pain associated with FBSS."

PROMISE participants will be randomized 1:1 to receive treatment with either SCS with OMM or OMM only. After a six-month observational phase, the study will compare the proportion of participants in the SCS group who report more than 50 percent reduction in low back-pain intensity, as measured by the Numeric Pain Rating Scale, with those in the OMM-only group. Health care utilization data collected will be used to develop cost analysis models for potential use in future studies evaluating the long-term economic impact of SCS.

"Medtronic is committed to advancing the understanding of its neurostimulation therapy in patients with low back pain resulting from FBSS," said Julie Foster, general manager and vice president, Pain Stimulation and Targeted Drug Delivery in the Neuromodulation business of Medtronic, Inc. "PROMISE provides the opportunity to assess not only the degree of pain relief provided by SCS plus OMM compared to OMM alone in failed back surgery patients, but also to evaluate the economic and quality of life impact of this treatment by looking at such important measures as sleep, ability to work and changes in pain medication."

More information about the PROMISE study, including enrollment information, can be obtained at http://clinicaltrials.gov/ct2/show/NCT01697358?term=medtronic+and+back+pain&rank=1.

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.

2Breivik H, Collett B, Ventafridda V, Cohen R, Gallagher D. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. Eur J Pain 2006;10:287-333.

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4Chan C, Peng P. Review Article: Failed Back Surgery Syndrome. Pain Medicine 2011; 12: 577-606.

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HUG#1673354

Source URL (retrieved on *07/10/2014 - 1:54am*):
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