Medtronic News

Medtronic Launches Novel Clinical Trial Evaluating Spinal Cord Stimulation Therapy for Heart Failure

Defeat-HF Trial Aims to Slow HF Progression with Neurostimulation

MINNEAPOLIS, Jul 29, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced the global launch of the Defeat-HF (Determining the Feasibility of Spinal Cord Neuromodulation for the Treatment of Chronic Heart Failure) clinical trial. It is the industry's first prospective, randomized study evaluating the clinical feasibility of spinal cord stimulation (SCS), or neurostimulation, to improve clinical signs and symptoms of heart failure.

More than 5 million Americans and 22 million people worldwide have heart failure and it is a leading cause of hospitalization. Heart failure stimulates the sympathetic nervous system further progressing the disease. The Defeat-HF study will evaluate whether SCS can restore the natural balance between the sympathetic and parasympathetic nervous systems to improve blood flow, reduce inflammation and restore the heart's dimensions and function. The study will be conducted under an Investigational Device Exemption (IDE) in the United States.

"The unique collaboration of cardiologists and neurosurgeons on this novel feasibility trial has the potential to identify new technologies to treat more heart failure patients and specifically slow the deterioration of patients with advanced heart failure," said Cecilia Linde, M.D., Ph.D., Defeat-HF investigator and cardiologist at the Karolinska University Hospital in Stockholm, Sweden, who enrolled the first patient. The implantation was performed by neurosurgeons Prof. Bengt Linderoth, M.D., and Dr. Goran Lind, M.D.

Neurostimulation uses an implantable pulse generator (IPG), or neurostimulator, similar to a cardiac pacemaker, with a lead, or thin wire, connecting the device to the spinal cord to deliver low-intensity electrical pulses. The procedure includes percutaneous placement of the leads in the spinal column and the stop-watch-sized neurostimulator is typically implanted in the abdomen.

"This clinical trial will explore the potential for neurostimulation to help physicians provide additional device therapy options for the growing population of heart failure patients," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "Medtronic is proud to continue our leadership in the heart failure therapy and diagnostic market and is uniquely positioned to evaluate this disruptive technology."

As the pioneer in neuromodulation, Medtronic technologies already have gained significant medical acceptance, including SCS for chronic back and leg pain, deep brain stimulation for movement disorders and sacral nerve stimulation for the debilitating symptoms of overactive bladder. There are also neurostimulation therapies approved under Humanitarian Device Exemptions (HDEs) for severe obsessive-compulsive disorder and the nausea and vomiting associated with severe gastroparesis. There are more than 20 years of literature supporting SCS for cardiovascular applications.

About Defeat-HF

The prospective, randomized, feasibility trial is expected to enroll NYHA Class III systolic heart failure patients at up to 15 centers worldwide. All patients are implanted with a Medtronic PrimeADVANCED(TM) neurostimulator and followed for 12 months. In this trial, the device delivers stimulation for 12 hours a day.

The trial will measure improvement in heart failure metrics such as heart size and muscle wall thickness, the heart's efficiency in carrying oxygen, and HF symptoms like fatigue, shortness of breath, and quality of life. Metrics will be measured throughout the trial.

Note: The Medtronic PrimeADVANCED(TM) neurostimulator is approved for severe chronic pain from conditions including back and leg pain, complex regional pain syndrome and painful neuropathy.It is limited to investigational use in heart failure patients.

About Heart Failure

Heart failure occurs when the heart muscle is unable to pump effectively to meet the body's need for blood and oxygen. Heart failure is the only major cardiac disorder that is increasing in prevalence. Heart failure is the most costly cardiovascular disease in the United States at an estimated $40 billion per year. Heart failure accounts for more than one million hospitalizations annually, more than all forms of cancer combined.

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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