New Clinical Trial First To Evaluate Effectiveness of CRT-P in Symptomatic Heart Failure Patients with Mild-to-Moderate Structural Heart Disease

The Associated Press

Medtronic-Sponsored Study Aims to Support Worldwide Indication Expansion for CRT-P in a Significantly Underserved Heart Failure Patient Population

MINNEAPOLIS - Jan. 10, 2013 - Medtronic, Inc. (NYSE: MDT) today announced the first patient enrollment in MIRACLE EF, a global clinical trial that will evaluate the effectiveness of cardiac resynchronization therapy-pacemakers (CRT-Ps) in delaying the progression of heart failure in symptomatic patients with mildly reduced heart pumping function. This large study will be the first to evaluate CRT-P in a widely underserved patient group - those who have a slightly reduced left ventricular ejection fraction (LVEF) in the range of 36 to 50 percent, which means that their hearts work somewhat more efficiently than heart failure patients who are currently indicated for implanted device therapy because of their lower LVEF.

The CRT-P devices used in MIRACLE EF are not approved by the FDA for the patient population being studied. Edward Schloss, M.D., FACC, performed the first implant at The Christ Hospital's Lindner Research Center in Cincinnati; primary investigator for the site is Greg Egnaczyk, M.D., Ph.D., FACC.

"Previous studies have proven the real-world therapeutic benefits of CRT in treating mildly to severely symptomatic heart failure patients with moderately to severely reduced cardiac pumping capacity and electrical dyssynchrony," said Professor Cecilia Linde, M.D., Ph.D., of Karolinska University Hospital in Stockholm, and worldwide principal investigator in the trial. "Through this large global study we hope to further our research on the overall effectiveness of CRT-P by showing its benefit in treating patients with mild-to-moderate heart failure symptoms, but with milder impairment of heart pumping capacity than previously studied."

Approximately 275 centers throughout the world, in regions including the United States, Canada, Europe, Japan and developing markets, will enroll up to 2,300 patients who will receive a Medtronic Consulta® CRT-P in this prospective, double-blind, randomized controlled trial. Patients will be followed for at least two years or until close of the study. Medtronic anticipates the trial will take four to five years to complete. The effectiveness of CRT-P in this patient population will be assessed using a composite endpoint of time to first event, defined as all-cause mortality or heart failure hospitalization.

"We are hopeful that, when completed, MIRACLE EF will influence clinical practice guidelines regarding the use of advanced cardiac resynchronization devices and

potentially lead to another expanded indication for Medtronic CRT devices," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic. "We look forward to the positive implications these findings could have on heart failure patients whose disease is less pronounced, yet who still experience symptoms and need advanced therapeutic solutions."

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

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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