Medtronic News

Five-Year Analysis of Pivotal REVERSE Trial Demonstrates Long-Term Clinical Benefits of Medtronic CRT-D Therapy in Mild Heart Failure Patients

Low Mortality and Heart Failure Hospitalization Sustained at 5-Years Post Implant with Medtronic CRT-D Devices

MUNICH, GERMANY – August 27, 2012 – Medtronic, Inc. (NYSE: MDT) today announced findings from a new clinical analysis

of the pivotal REVERSE (Resynchronization Reverse Remodeling in Systolic Left Ventricular Dysfunction) trial, which demonstrated that its cardiac resynchronization therapy (CRT) devices are associated with low mortality and heart failure hospitalization rates over 5 years, post-implant. This is the first – and longest – study of its kind to show that CRT results in significant structural changes to the heart in patients with mild disease (at 2 years following implant), and also had positive, enduring long-term effects. The 5-year data was presented today at the European Society of Cardiology's ESC Congress 2012 in Munich.

"These findings show, for the first time, the overall magnitude of the long-lasting, lifesaving benefits of CRT in a mildly symptomatic patient population," said Cecilia Linde, M.D., Ph.D., of Karolinska University Hospital in Stockholm, and principal investigator in the trial who presented the new data at ESC. "This noteworthy data adds to the growing body of evidence further validating the clinical benefits of early intervention with CRT and confirms the sustaining benefit that patients can continue to receive over a 5-year time-span."

Throughout the REVERSE study, the benefits of CRT persisted, indicating that the device therapy reduces disease progression in patients with mildly symptomatic (New York Heart Association/NYHA-designated Class I and II) heart failure for at least 5 years following implant. Patients whose CRT was immediately activated at the beginning of the trial experienced a 5-year mortality rate of 13.5 percent, and a death plus heart failure-related hospitalization rate of 28.1 percent. These rates are lower than those observed in other landmark CRT clinical trials with similar patient populations[1].

Heart failure patients suffer from enlarged hearts and, in the study, CRT therapy was shown to reverse this cardiac enlargement and sustain the reversal over time, as measured by the left ventricular end systolic volume index (LVESVi). In REVERSE, the change was greatest within the first 2 years of therapy and thereafter sustained.

"The REVERSE trial continues to provide the medical community with valuable, real-world insight on the benefits of CRT in providing optimal treatment to patients with early-stage heart failure," said David Steinhaus, M.D., vice president, general manager and medical director for the Cardiac Rhythm Disease Management business. "We are committed to providing physicians with the most advanced medical devices – backed by strong clinical data – to treat heart failure patients across the continuum of care, whether in the earliest or most severe stages of disease."

Recent Key Findings on Cost-Effectiveness

The REVERSE study findings also support the cost-effectiveness of CRT in patients with mild disease, given the acceptable rate of adverse events in this study population exhibited in the trial. In May, Medtronic presented findings from an economic analysis of the landmark RAFT (Resynchronization/Defibrillation in Ambulatory Heart Failure Trial) trial, showing that CRT is a costeffective treatment for mildly symptomatic heart failure patients. The findings revealed a $33,025 (USD) cost per Quality Adjusted Life Year (QALY) gained using Medtronic CRTs in mild to moderate, NYHA-designated Class II-III heart failure patients, substantially lower than the benchmark for therapy cost effectiveness of other serious chronic conditions that cost at least $50,000 per QALY gained.

Medtronic CRT-D Expanded Indication Approval

Earlier this year, the U.S. Food & Drug Administration (FDA) expanded the indication for Medtronic's CRT-D (cardiac resynchronization therapy with defibrillation) devices to treat NYHA Class II heart failure patients with a left ventricular ejection fraction (LVEF) of less than or equal to 30 percent, left bundle branch block (LBBB), and a QRS duration greater than or equal to 130 milliseconds. The expanded indication, which was granted based on data from the REVERSE and RAFT clinical trials, addresses a serious unmet need by enabling treatment with CRT-D in indicated patients in the earlier stages of heart failure, before their symptoms start impacting their quality of life.

Sudden cardiac arrest (SCA) is responsible for more than 60 percent of deaths among patients with mild-to-moderate heart failure. However, research suggests that earlier intervention with CRT-D can decrease the risk of morbidity and mortality in this mildly symptomatic patient population. CRT-D therapy works by resynchronizing the contractions of both ventricles by sending

tiny electrical impulses to the heart muscles, which improves the heart's blood-pumping ability. The device also has defibrillation capability, allowing for termination of life-threatening ventricular arrhythmias.

About the REVERSE Trial

With 610 patients studied, REVERSE was a prospective, randomized, double-blind study designed to determine whether CRT limited heart failure progression compared to optimal medical therapy alone among NYHA Class I or II heart failure patients with QRS ≥120ms, and LVEF ≤40 percent. Patients were implanted with a CRT device (+/-defibrillator) and were randomized to CRT ON or CRT OFF in a 2-to-1 ratio. By 24 months all subjects were programmed to CRT ON and followed through 5 years. One of the objectives of the study was to describe the 5 year results in the 419 patients assigned to CRT ON. The mean follow up time was 4.5 years.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

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] Each of these trials involved distinct clinical study protocols

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