Medtronic News

New Data from Landmark Study Shows Cost-Effectiveness of Medtronic Life-Saving CRT-D Therapy in Mildly Symptomatic Heart Failure Patients

Study Reinforces Clinical and Economic Validity of Expanded Indication for Medtronic CRT-D Devices

MINNEAPOLIS & BOSTON--(BUSINESS WIRE)--May. 11, 2012-- Medtronic, Inc. (NYSE: MDT) today announced findings from an economic analysis of the landmark RAFT (Resynchronization / Defibrillation in Ambulatory Heart Failure Trial) trial demonstrating that cardiac resynchronization therapy with defibrillation (CRT-D) is a cost-effective treatment for mildly symptomatic heart failure patients. The findings showed a $33,025 (USD) cost per Quality Adjusted Life Year (QALY) gained using Medtronic CRT-Ds in a mild, New York Heart Association (NYHA)-designated Class II-III heart failure patient population, substantially lower than the benchmark for therapy cost effectiveness of other serious chronic conditions that cost at least $50,000 per QALY gained.1 QALY is a measure of the quantity and quality of life.

Presented today at Heart Rhythm 2012, the Heart Rhythm Society's 33rd Annual Scientific Sessions, the RAFT economic analysis is the only study to demonstrate cost-effectiveness in conjunction with the significant mortality benefit of CRT-D in mildly symptomatic heart failure patients. It complements the expansive body of clinical evidence for CRT-D illustrating the benefits of the Medtronic CRT-D portfolio of devices, as shown previously in the Medtronic-sponsored REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) trial.

In the RAFT economic analysis, patients who received CRT-D were estimated to gain more than one quality-adjusted life year (1.07) at an additional cost of $35,308 (USD) over a lifetime horizon, the typical time period commonly cited by health economists.

"The large-scale RAFT trial has provided us with a wealth of clinical insight into the overall benefits of CRT-D in treating mild heart failure, proving that this advanced therapy significantly decreases mortality and reduces heart failure hospitalization rates with an economic value to the healthcare system as a whole," said George Wells, Ph.D., University of Ottawa Heart Institute, Ottawa, Canada.

Approximately 6 million people in the United States suffer from heart failure, and the estimated cost for treating the life-threatening condition is almost $40 billion per year.2 In line with numerous clinical trials showing that CRT-D is a cost-effective treatment approach in treating moderate-to-severe disease, this new data confirms it is also associated with a cost-effectiveness benefit per QALY gained in mild heart failure patients.

Last month, the U.S. Food & Drug Administration (FDA) approval expanded the indication for Medtronic's CRT-D 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 fulfills 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.

"The recent FDA approval expanding the indication of our CRT-D devices – coupled with this strong economic data – showcases our commitment to treating heart failure and enhancing patient outcomes at every stage of care with our innovative portfolio of CRT-D therapies," said David Steinhaus, M.D., Vice President and General Manager, Heart Failure, and Medical Director for the Cardiac Rhythm Disease Management business, Medtronic. "With the rising cost of healthcare significantly impacting our global economy, it is critically important to provide high-value, safe, effective therapies like CRT-D, that provide significant improvements at cost thresholds deemed acceptable to health care decision makers, as this analysis demonstrated."

The economic analysis assessed the healthcare-related costs and QALYs of 1,798 patients randomized to receive CRT-D or

ICD therapy extrapolated across a lifetime horizon, which was facilitated by an economic model that combined RAFT patient data with long-term data on the longevity of the medical devices. Cost in regard to QALYs was discounted at 3 percent per year. Healthcare-related costs examined included the treatment device (plus any replacements), hospitalization (both cardiovascular and non-cardiovascular related), pharmaceutical treatments, physician visits and long-term care, and were calculated using U.S. expenditures.

About the RAFT Trial

The RAFT trial, sponsored by the Canadian Institutes of Health Research and Medtronic, is a double-blinded, randomized, controlled trial, and showed that CRT-D significantly reduced mortality for mildly symptomatic heart failure patients (NYHA Class II): 29 percent when compared to patients treated with guideline-recommended implantable ICDs and medical therapy (p=0.006; HR=0.71). The study also demonstrated a significant reduction (30 percent) in heart failure hospitalizations for this Class II population (p=0.003; HR=0.70), consistent with previously published studies. It involved 1,798 patients in Canada, Europe and Australia. All patients were followed for at least 18 months, and had an average follow-up of 40 months, making it the longest follow-up and largest patient months-of-experience of any randomized controlled trial of CRT therapy.

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.

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.

1 The Economic Argument for Disease Prevention: Distinguishing Between Value & Savings. Partnership for Prevention. February 2009. Retrieved on April 9, 2012 from http://www.prevent.org.
2American Heart Association / American Stroke Association, Heart Disease and Stroke Statistics, 2010 Update.

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Medtronic, Inc.
Kathleen Janasz
Public Relations
763-526-3676
or
Jeff Warren
Investor Relations
763-505-2696

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