Medtronic News

Landmark Medtronic-Supported Study Shows CRT-D Reduced Mortality by 29 Percent in Mildly Symptomatic Heart Failure Patients

RAFT Clinical Trial First to Show Significantly Reduced Mortality in Mildly Symptomatic Patients Study Has Longest Follow-Up and Largest Patient Months of Experience of Any CRT Therapy Study

MINNEAPOLIS & CHICAGO, Nov 14, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced that the landmark RAFT (Resynchronization/Defibrillation for Ambulatory Heart Failure Trial) clinical trial shows Medtronic cardiac resynchronization therapy-defibrillators (CRT-Ds) significantly reduced mortality for mildly symptomatic heart failure patients (NYHA Class II) by 29 percent when compared to patients treated with guideline-recommended implantable cardioverter-defibrillators (ICDs) and medical therapy. The RAFT data also demonstrated a significant reduction (27 percent) in combined mortality and heart failure hospitalizations for this population consistent with previously published studies. The use of Medtronic CRT devices for mildly symptomatic heart failure patients (NYHA Class II) is investigational and not an approved use in the United States. The findings from the RAFT clinical trial were released at the late-breaking clinical science session at the Scientific Sessions 2010, the annual congress of the American Heart Association in Chicago and published online in the *New England Journal of Medicine*.

"These landmark findings demonstrate that earlier intervention with CRT-D, in addition to guideline-recommended medical and ICD therapy, saves lives in this patient population," said Anthony Tang, M.D., RAFT principal investigator, professor of medicine at the University of British Columbia and adjunct professor of medicine at the University of Ottawa Heart Institute in Ottawa, Canada. "Even for patients without major restrictions from their heart failure, CRT has been shown to slow the progression of their disease and reduce heart failure hospitalizations."

More than 22 million people worldwide - including 500,000 Canadians and 6 million patients in the United States1 - have heart failure, a condition in which the heart cannot adequately pump blood through the body. Cardiovascular mortality has declined over the last three decades; however, the mortality rate for heart failure is rising.2 Additionally, heart failure is the most costly cardiovascular disease in the United States at an estimated cost of nearly $40 billion per year.1

Cardiac resynchronization therapy reduces heart failure symptoms as well as hospitalizations and mortality for some patients with moderate to severe heart failure (New York Heart Association, or NYHA, Class III and ambulatory Class IV). The RAFT trial investigated whether patients with mild to moderate heart failure (NYHA Class II and III) could benefit from cardiac resynchronization therapy in conjunction with ICD and medical therapy. Both the mortality alone and the combined mortality and heart failure hospitalization endpoints for all patients in the study were reduced by 25 percent.

"This Medtronic-supported research is the first to show the significant lifesaving value of CRT-D for mildly symptomatic heart failure patients and builds upon the growing body of evidence calling for guideline changes," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "Our goal is to ensure heart failure patients who could benefit from our therapies are able to receive them."

Medtronic has supported seven major heart failure studies that have contributed to guidelines, including SCD-HeFT, REVERSE, MIRACLE, MIRACLE ICD, MIRACLE ICD II, MUSTIC, and CARE HF studies. First published in

December 2008, the Medtronic-sponsored REVERSE (Resynchronization Reverse Remodeling in Systolic Left Ventricular Dysfunction) clinical trial was the industry's first study showing the benefit of CRT for mildly symptomatic patients.

About RAFT

A double-blinded, randomized, controlled trial, RAFT was led by the University of Ottawa Heart Institute and jointly supported by grants from the Canadian Institutes of Health Research (CIHR) with financial support from Medtronic of Canada. A total of 1,798 mild to moderate heart failure (NYHA Class II and III) patients with ejection fraction of less-than or equal to 30 percent, and a QRS duration greater-than or equal to 120 were enrolled in the study at 34 centers in Canada, Europe, Turkey and Australia. Eighty percent (1,438) of the patients had NYHA Class II symptoms at enrollment. Patients were followed 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 study of CRT therapy. The study used Medtronic ICDs and CRT-Ds. The primary outcome was a composite of total mortality and heart failure hospitalization; secondary outcomes included death by any cause, death from cardiovascular cause and hospitalization for heart failure.

Caution: The use of Medtronic CRT devices for mildly symptomatic heart failure patients (NYHA Class II) is investigational and not an approved use in the United States.

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.

1 American Heart Association / American Stroke Association, Heart Disease and Stroke Statistics, 2010 Update
2 NHLBI, M.a.M., 2007 chart book on cardiovascular, lung, and blood diseases http://www.nhlbi.nih.gov/resources/docs/07-chtbk.pdf

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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