Medtronic News

# Biventricular Pacing Reduces Symptoms and Improves Quality-of-Life in AV Block Patients with Heart Failure and Reduced Pumping Function

*New Medtronic Data Show Additional Clinical Advantages in Pacing Both Ventricles Versus Conventional Right-Ventricular Pacing*

MINNEAPOLIS and DENVER - May 11, 2013 - Medtronic, Inc. (NYSE: MDT) today announced new data demonstrating that simultaneously pacing the lower chambers of the heart, or biventricular (BiV) pacing with a cardiac resynchronization therapy (CRT) device, significantly improves heart failure symptoms and quality of life in a subset of heart failure patients.

Findings from the BLOCK HF clinical trial, presented as late-breaking data today at Heart Rhythm 2013, the Heart Rhythm Society's 34th Annual Scientific Sessions, showed a marked reduction in heart failure-related symptoms for patients with atrioventricular (AV) block and left ventricular (LV) systolic dysfunction at six, 12, 18 and 24 months treated with BiV pacing as opposed to conventional right-ventricular (RV) pacing. Additionally, the data revealed a considerable improvement in quality of life among BiV-paced patients at six and 12 months. Primary results from BLOCK HF were recently published in *The New England Journal of Medicine*. Medtronic CRT devices are not currently approved in the United States for patients with AV block with left ventricular dysfunction; the results from BLOCK HF will serve as the basis for an application to the FDA seeking an expanded indication for this patient population.

"These new data add to the growing body of evidence supporting the use of BiV pacing for treating patients who have AV block and left ventricular dysfunction who are indicated under current clinical guidelines for permanent RV pacing with a pacemaker," said Anne B. Curtis, M.D., lead investigator and Chair of the Department of Medicine at the University at Buffalo School of Medicine and Biomedical Sciences, Buffalo, NY. "The BLOCK HF findings have previously demonstrated that BiV pacing delays disease progression, prevents heart failure-related events and preserves cardiac function in this patient population. The findings presented today confirm two additional, yet equally important clinical benefits associated with this innovative therapy - symptom and quality-of-life improvement."

At six months, 14 percent more patients randomized to BiV pacing improved compared to patients in the RV arm. Similar positive findings comparing improvement between arms were reported at later points and sustained over a two year period in the patients who received BiV pacing. These results were measured using the Packer Clinical Composite Score (CCS), which analyzes a patient's condition as improved, unchanged or worsened using variables including death, heart failure hospitalization, a patient global assessment questionnaire, and change in symptoms as measured by New York Heart Association (NYHA) heart failure class. Additionally, increased improvement in NYHA heart failure classification with BiV pacing was seen at 12 months post-randomization.

BiV patients also experienced an average improvement of five points in quality-of-life (QoL) score at six months post-randomization. These QoL findings, measured by the Minnesota Living with Heart Failure Questionnaire, are based on a more subjective analysis of the ways heart failure affects the physical, emotional, and social dimensions of a patient's quality-of-life.

"RV pacing has been considered the gold standard for decades in treating patients with AV block; however, findings from the BLOCK HF trial continue to exhibit better overall outcomes with BiV pacing via CRT devices for these patients," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic.

More than 800,000 Americans have AV block. While RV pacing via a single or dual chamber pacemaker helps restore heart function in patients with AV block (in which the electrical signals do not travel between the top and bottom chambers of the

heart), smaller studies suggest that in patients with both AV block and LV dysfunction, RV pacing may escalate the progression of heart failure.1,2

About BLOCK HF

BLOCK HF (Biventricular versus Right Ventricular Pacing in Patients with Left Ventricular Dysfunction and Atrioventricular Block) is a prospective, multi-center, randomized, double-blind, controlled trial that evaluated patients with AV block and LV dysfunction (ejection fraction less than or equal to 50 percent), New York Heart Association (NYHA) Class I, II or III and who met standard indications for ventricular pacing. It enrolled 918 patients from 60 centers in the United States and Canada; of these, 691 patients were randomized to receive either BiV (349) or RV (342) pacing. The primary results, published in the April 25, 2013, edition of *The New England Journal of Medicine*, showed a 26 percent relative risk reduction in the composite of death, healthcare utilization visits requiring IV heart failure therapy, and significant increase in left ventricular end systolic volume (LVESVi, a measure of cardiac function) among patients receiving BiV pacing.

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. 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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1 Kindermann M, et al. Biventricular Versus Conventional Right Ventricular Stimulation for Patients With Standard Pacing Indication and Left Ventricular Dysfunction: The Homburg Biventricular Pacing Evaluation (HOBIPACE). J Am Coll Cardiol. 2006;47(10):1927-1937. Available at http://content.onlinejacc.org/article.aspx?articleid=1137582.

2 Martinelli Filho M, et al. Conventional versus biventricular pacing in heart failure and bradyarrhythmia: the COMBAT study. J Card Fail. 2010;16(4):293-300. Available at http://www.onlinejcf.com/article/S1071-9164(09)01228-7/abstract.

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