Medtronic News

Significantly Better Patient Outcomes Gained from Pacing Both Ventricles in Patients with AV Block and Reduced Pumping Function

Medtronic Biventricular Pacing Reduces Risk of Death and Heart Failure Visits by 27 Percent, Demonstrating Superiority and Real-World Clinical Benefits Compared to Right Ventricular Pacing

MINNEAPOLIS and LOS ANGELES - Nov. 6, 2012 - Medtronic, Inc. (NYSE: MDT) today announced interim findings from the BLOCK HF trial, which show that biventricular (BiV) pacing may offer a significant clinical advantage and improved patient outcomes over conventional right ventricular (RV) pacing among patients with left ventricular (LV) systolic dysfunction and atrioventricular (AV) block who are indicated for a pacemaker. Presented as a late-breaking clinical trial at the American Heart Association's 2012 Scientific Sessions, BLOCK HF shows a 27 percent relative risk reduction in the composite of death and healthcare utilization visits requiring intravenous (IV) heart failure therapy among this patient population. The CRT devices used in the BLOCK HF trial are not approved by the FDA for the patient population studied at this time.

While RV pacing (via a single or dual chamber pacemaker) helps restore heart function in patients with AV block, recent studies suggest that in patients with both AV block and LV dysfunction, RV pacing may escalate the progression of heart failure (HF).1 Approximately 4.7 million Americans are indicated for a pacemaker, and of these, more than 800,000 have AV block, which occurs when the electrical signals are blocked between the top and bottom chambers of the heart, reducing the organ's ability to function normally.

Additional results from BLOCK HF demonstrate 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 index (LVESVi, a measure of cardiac function) among the patients receiving BiV pacing, meeting the trial's primary objective. These findings are preliminary, and other secondary endpoints will be evaluated and reported on in the future.

"The BLOCK HF trial is the first to show better patient outcomes with BiV pacing in patients who have AV block and heart failure, who would typically receive a pacemaker under the current guidelines," said Anne Curtis, M.D., lead study investigator and chair of the Department of Medicine at the University at Buffalo School of Medicine and Biomedical Sciences, Buffalo, NY. "These data demonstrate the potential for significant, real-world clinical benefits of biventricular pacing in helping delay the onset or worsening of heart failure symptoms in patients with a slow-beating heart."

"Today, patients are implanted with a traditional pacemaker when they present with AV block and reduced pumping capacity, but BLOCK HF demonstrates that these patients had better outcomes when treated with biventricular pacing via a cardiac resynchronization therapy device," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic. "Not only did their chance of death or hospitalization shrink significantly with biventricular pacing, but it potentially slows the overall progression of heart failure, which significantly affects patients' quality of life."

Heart failure is a major heath issue impacting the U.S. population, with nearly 6 million Americans currently diagnosed and approximately 670,000 new cases confirmed each year.2 This debilitating and often deadly disease has been estimated to cost the United States between $26 billion and $56 billion per year2, which includes the costs of healthcare services, medications and lost productivity.

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. NYHA class at enrollment consisted of 16 percent Class I, 57 percent Class II and 27 percent Class III. Patients were followed for up to 102 months, with a mean follow-up of approximately 36 months.

The trial utilized a Bayesian statistical design; objectives were evaluated using metrics consistent with Bayesian methodology.

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 American Heart Association. Heart Disease and Stroke Statistics - 2012 Update. Circulation. Available at http://americanheart.org/presenter.jhtml?identifier3000090.

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