Medtronic News

The New England Journal of Medicine: Medtronic Biventricular Pacing Delivers Better Patient Outcomes for Those with AV Block and Reduced Pumping Function

MINNEAPOLIS - April 24, 2013 - Biventricular (BiV) pacing with Medtronic, Inc. (NYSE: MDT) cardiac resynchronization therapy (CRT) devices 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. Results from the Medtronic-sponsored BLOCK HF trial show a 26 percent relative risk reduction in the composite of death, healthcare utilization visits requiring intravenous (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. The results are published in the April 25, 2013, edition of *The New England Journal of Medicine*.

Under current guidelines, patients with AV block and reduced pumping capacity are indicated for a dual or single chamber pacemaker. While RV pacing via a traditional pacemaker restores heart function in these patients, recent studies suggest that in patients with both AV block and LV dysfunction, sustained RV pacing may escalate the progression of heart failure (HF).1 More than 800,000 Americans 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.

"The BLOCK HF results should lead to a reassessment of the guidelines and the way we treat these patients," 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. "As a result of this trial, we now know that heart failure hospitalizations and mortality may be reduced for patients with AV block and heart failure if they receive biventricular pacing."

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.

The CRT devices used in the BLOCK HF trial are not approved by the FDA for the patient population studied at this time.

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.

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. (<u>www.medtronic.com</u>), 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.

-end-

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.

Contacts:

Tracy McNulty
Public Relations
+1-763-526-2492

Jeff Warren Investor Relations +1-763-505-2696

https://news.medtronic.com/2013-04-24-The-New-England-Journal-of-Medicine-Medtronic-Biventricular-Pacing-Delivers-Better-Patient-Outcomes-for-Those-with-AV-Block-and-Reduced-Pumping-Function