Medtronic News

Medtronic CRT Devices Now Approved to Treat Patients with AV Block and Reduced Heart Function

Landmark BLOCK HF Trial Demonstrates Clinical Benefits of Biventricular Pacing in New Patient Population

MINNEAPOLIS - April 10, 2014 - Medtronic, Inc. (NYSE: MDT) today announced that the U.S. Food and Drug Administration (FDA) approved an expanded indication for biventricular (BiV) pacing with Medtronic cardiac resynchronization therapy-pacemakers and -defibrillators (CRT-P and CRT-D). Medtronic CRT devices are now approved to treat patients with atrioventricular (AV) block and left ventricular (LV) systolic dysfunction, reducing heart failure hospitalizations and mortality, and improving cardiac function in these patients.

The expanded indication allows patients designated as New York Heart Association (NYHA) Class I, II and III with AV block that are expected to require a high percentage of ventricular pacing, and who have an ejection fraction (measure of the heart's pumping ability) less than or equal to 50 percent, to receive BiV pacing via Medtronic CRT devices.

The FDA's approval was based on the landmark BLOCK HF clinical trial, which demonstrated significant clinical advantages of BiV pacing compared with traditional right ventricular (RV) pacing in this patient population, including a 27 percent relative risk reduction in the composite study endpoint of heart size, heart failure hospitalizations and mortality.

"For patients with AV block and LV dysfunction, traditional RV pacing may escalate the progression of heart failure," said Anne B. Curtis, M.D., BLOCK HF 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 clinical trial provided strong clinical evidence validating the safety and efficacy of BiV pacing in this patient population."

More than 1 million Americans have AV block, which reduces the heart's ability to properly function by blocking the electrical signals between its top and bottom chambers. Symptoms of the condition are fainting, dizziness and shortness of breath. A debilitating and often deadly disease, heart failure will cost the United States an estimated $32 billion in 2013, with projections showing a 120 percent increase in cost by 2030 for a total of $70 billion1.

"Medtronic is pleased with the FDA's decision to expand the use of BiV pacing with Medtronic CRT-P and CRT-D devices in this new patient population," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic. "We have more than a decade of evidence showing that CRT improves quality of life for heart failure patients, and we now have also demonstrated improved outcomes for AV block patients with these devices, as well."

About BLOCK HF

BLOCK HF (Biventricular versus Right Ventricular Pacing in Patients with Left Ventricular Dysfunction and Atrioventricular Block), published in *The New England Journal of Medicine*, 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), NYHA Class I, II or III and who met standard indications for ventricular pacing. The primary results showed a 27 percent relative risk reduction in the composite study endpoint of death, healthcare utilization visits requiring IV heart failure therapy, and significant increase in left ventricular end systolic volume (LVESVI, a measure of cardiac structure) 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.

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 American Heart Association. Heart Disease and Stroke Statistics - 2013 Update. Circulation. Available at http://circ.ahajournals.org/content/127/1/e6.full.pdf+html.

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