Medtronic News

FDA Advisory Panel Recommends Expanded Indication for Medtronic CRT Devices in Patients with AV Block and Reduced Heart Function

Thomson Reuters ONE via COMTEX) --Panel Vote Underscores Clinical Benefits of Biventricular Pacing for Better Patient Outcomes and Improved Quality of Life

MINNEAPOLIS - Oct. 8, 2013 - The U.S. Food and Drug Administration's (FDA) Circulatory Systems Devices Advisory Panel today voted that biventricular (BiV) pacing with Medtronic, Inc. (NYSE: MDT) devices is beneficial for treating patients who have atrioventricular (AV) block and left ventricular (LV) systolic dysfunction, compared to conventional right ventricular pacing. The panel voted that the overall clinical benefits outweigh the risks in treating this specific patient population (Yes: 4 votes; No: 3 votes; Abstain: 1 vote). The panel's favorable recommendation is based on data from the landmark BLOCK HF clinical trial, which used Medtronic cardiac resynchronization therapy-pacemakers and -defibrillators (CRT-P and CRT-D).

Most patients with AV block are currently indicated to receive conventional right ventricular (RV) pacing via a single or dual chamber pacemaker or implantable cardioverter-defibrillator (ICD). However, in the BLOCK HF clinical trial, BiV pacing 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 index (LVESVI, a measure of cardiac structure); and

- improvements in both cardiac function and quality of life.

The advisory panel voted in favor of Medtronic CRT-P and CRT-D devices in this patient group based on the technology's strong safety (Yes: 6 votes, No: 1 votes) and efficacy (Yes: 7 votes, No: 0 votes) profiles. The FDA now will consider the panel's feedback as it reviews the request from Medtronic to expand treatment indications for its CRT-P and CRT-D devices to include New York Heart Association (NYHA) Class I, II and III heart failure, patients with pacemaker-indicated second or third degree AV block, or first degree AV block where a requiment for a high percentage of ventricular pacing is clear, and LV ejection fraction less than or equal to 50 percent.

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. While RV pacing helps restore heart function in patients with AV block, studies suggest that in patients with both AV block and LV dysfunction, this type of pacing may escalate the progression of heart failure1 2. 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 billion3.

"As the longest running trial of its kind, BLOCK HF has shown superior long-term outcomes of BiV pacing 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. "As the regulatory process continues, we look forward to working with the FDA to expand the use of our CRT devices to treat this specific patient population."

"The results of BLOCK HF offer us a potential new treatment paradigm for heart failure patients with AV block," said Anne 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. "This new approach could fill an unmet need for these patients."

Caution: Medtronic CRT devices are not currently approved in the United States for patients with AV block with left ventricular dysfunction.

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. 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 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. Findings also showed a marked reduction in heart failure-related symptoms for patients treated with BiV pacing as opposed to RV pacing. Additionally, the data revealed a considerable improvement in quality of life among BiV-paced patients at six and 12 months.

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 The DAVID Trial Investigators. Dual-Chamber Pacing or Ventricular Backup Pacing in Patients with an Implantable Defibrillator. JAMA. 2002;288:3115-3123.

2 Sweeney MO et al. Adverse Effect of Ventricular Pacing in Heart Failure and Atrial Fibrillation Among Patients with Normal Baseline QRS Duration in a Clinical Trial of Pacemaker Therapy for Sinus Node Dysfunction. Circulation. 2003;107:2932 - 2937.

3 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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