Medtronic News

Late Breaking Clinical Trial Reveals Reduced Risk of Atrial Fibrillation for Patients with Medtronic Devices Featuring AdaptivCRT

Thomson Reuters ONE via COMTEX) --Long-Term Clinical Trial Results Further Emphasize Safety and Added Benefits of Medtronic Proprietary Feature

MINNEAPOLIS and ORLANDO - Sept. 23, 2013 - Medtronic, Inc. (NYSE: MDT) today announced clinical trial results showing that heart failure patients treated with its exclusive AdaptivCRT® feature experienced a nearly 50 percent reduction in atrial fibrillation (AF) risk. Pioneered by Medtronic, the AdaptivCRT technology is a feature on certain cardiac resynchronization therapy-defibrillators (CRT-Ds) that continually adjusts therapy to a patient's natural heart rhythms and minimizes the amount of unnecessary right ventricular (RV) pacing. The results were presented today as a late breaking clinical trial at the Heart Failure Society of America's 17th Annual Scientific Meeting.

While CRT has consistently been proven to improve heart failure-related symptoms, reduce heart failure hospitalizations and reduce mortality in select heart failure patients, some do not have a full response to the therapy. Heart failure is a progressive disease, in which patients are more likely than the general population to develop AF1, which is associated with increased healthcare utilization, worsening heart failure symptoms, higher mortality and is a common factor related to a lack of CRT response. In fact, there is a direct relationship between heart failure symptoms (as classified by New York Heart Association, NYHA, status) and prevalence of AF, progressing from 4 percent in those patients who are asymptomatic (NYHA class I) to 40 percent in those who are NYHA class IV.2 Previous research has shown that minimizing the amount of unnecessary RV pacing reduces AF risk.3 4 5

Because the AdaptivCRT technology utilizes the heart's natural rhythm to continuously adjust therapy, patients in the study who received AdaptivCRT experienced a 34 percent reduction in right ventricular pacing compared to conventional CRT. Long-term study outcomes presented today show that patients receiving the AdaptivCRT technology were at a 46 percent lower risk of spending 48 consecutive hours or more in AF compared to conventional CRT patients.

Earlier research showed that the use of the AdaptivCRT feature improves heart failure patients' response rate to cardiac resynchronization therapy, resulting in a projected 21 percent reduction in overall heart failure hospitalizations within the first year after implant, as compared to historical CRT trials.6 Today's presentation also reinforced the safety and effectiveness of the AdaptivCRT feature.

"The AdaptivCRT technology is a novel approach to CRT-D that continually and automatically adjusts the therapy to the heart rhythm for each individual patient," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Managements business at Medtronic. "The results of the Adaptive CRT trial will be significant as the 'baby boomer' population ages and becomes more vulnerable to heart failure and associated conditions such as atrial fibrillation."

The AdaptivCRT algorithm is included in the Medtronic Viva®portfolio of CRT-D devices, which have been available in the United States since May 2013 and in Europe since 2012.

About the Adaptive CRT Trial

The global Adaptive CRT trial is a prospective, multicenter, randomized, double-blind study designed to evaluate the clinical benefit of synchronized left ventricular pacing (sLVP) provided by the AdaptivCRT algorithm. The trial enrolled 522 patients who received a CRT device and were randomized to either receive the AdaptivCRT algorithm (treatment arm) or conventional CRT

with echocardiographic optimization of the pacing parameters (control arm) in a 2:1 ratio. All patients were followed at six and 12 months and subsequently every six months until study closure. Overall, the Adaptive CRT trial demonstrated non-inferiority of the AdaptivCRT algorithm to echocardiographically optimized CRT.

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.

-end-

1 Wang TJ, Larson MG, Levy D, et al. Temporal relations of atrial fibrillation and congestive heart failure and their joint influence on mortality: the Framingham Heart Study. Circulation. 2003;107:2920-5.

2 Andersen HR, Nielsen JC, Thomsen PE, Thuesen L, Mortensen PT, Vesterlund T et al. Long-term follow-up of patients from a randomised trial of atrial versus ventricular pacing for sick-sinus syndrome. Lancet 1997;350:1210-6.

3 Lamas, G, Lee, KL, Sweeney, MO, et al for the Mode Selection Trial in Sinus-Node Dysfunction N Engl J Med 2002; 346:1854-1862

4 Sweeney MO, Bank AJ, Nsah E, Koullick M, Zeng QC, Hettrick D, Sheldon T, Lamas GA; Search AV Extension and Managed Ventricular Pacing for Promoting Atrioventricular Conduction (SAVE PACe) Trial. Minimizing ventricular pacing to reduce atrial fibrillation in sinus-node disease. N Engl J Med 2007;357:1000-1008.

5 Maisel WH, Stevenson LW. Atrial fibrillation in heart failure: epidemiology, pathophysiology, and rationale for therapy. Am J Cardiol. 2003;91:2D-8D.

6 Tarab AD, et al. ISPOR 2012

Contacts:

Tracy McNulty

Public Relations

+1-763-526-2492

Jeff Warren

Investor Relations

+1-763-505-2696

Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1730373

---

https://news.medtronic.com/2013-09-23-Late-Breaking-Clinical-Trial-Reveals-Reduced-Risk-of-Atrial-Fibrillation-for-Patients-with-Medtronic-Devices-Featuring-AdaptivCRT