Medtronic News

Medtronic Announces First Implants in Largest-Ever, Global Trial of Cardiac Resynchronization Therapy

Post-Market Clinical Trial Will Assess Superiority of the AdaptivCRT® Feature Compared to Standard CRT

MINNEAPOLIS - Aug. 27, 2014 - Medtronic, Inc. (NYSE:MDT) today announced the first implants in a clinical trial that will compare patient and healthcare system outcomes - including patient mortality and hospitalizations - in heart failure patients who have cardiac resynchronization therapy (CRT) devices with the AdaptivCRT® feature enabled versus patients receiving standard CRT. The AdaptResponse trial will assess the superiority of the AdaptivCRT algorithm, which preserves normal heart rhythms and automatically adjusts to patients' needs to customize therapy; it is expected to be the largest trial of CRT to date, enrolling approximately 3,000 patients worldwide.

The primary endpoint of the AdaptResponse trial is a combination of all-cause mortality and the rate of medical intervention for worsening heart failure (decompensation). The trial also will examine the incidence of atrial fibrillation (AF) in enrolled patients; other secondary endpoints will assess patient quality of life measures as well as cost-effectiveness of CRT devices with the AdaptivCRT feature relative to standard CRT. Patients will receive a CRT-pacemaker or CRT-defibrillator equipped with the AdaptivCRT algorithm, and will be randomized 1:1 to either treatment (aCRT ON) or control (aCRT OFF) groups. Patients will be followed at three and six months after randomization, and then every six months until trial closure.

Patients will be enrolled at up to 200 centers in Europe, Latin America, the Middle East, Australia, Canada, India, Japan, South Korea, Taiwan and the U.S. The first implants in the trial were performed by Mark Castellani, M.D., at Sparrow Hospital in Lansing, Mich., and by Edward J. Schloss, M.D., at The Christ Hospital in Cincinnati. Bruce Wilkoff, M.D., director of Cardiac Pacing and Tachyarrhythmia Devices at the Cleveland Clinic, is chair of the AdaptResponse trial's steering committee.

About the AdaptivCRT Algorithm

The AdaptivCRT algorithm is the first significant advance to improve patient response rates to CRT since the advent of the therapy more than 10 years ago. The benefits of the algorithm were demonstrated in the Adaptive CRT Trial, a prospective, multicenter, randomized, double-blind clinical trial. Key findings from the original trial, sub-analyses and economic models recently presented at Heart Rhythm 2014 and Cardiostim 2014 showed:

- For patients with normal AV conduction, AdaptivCRT showed an increase in CRT response rate of 12 percent1at six months
- Patients with AdaptivCRT demonstrated a 21 percent reduction in heart failure hospitalizations2 as compared to historical CRT trials
- Patients with the AdaptivCRT technology demonstrated a 46 percent reduced risk of AF3, and a 61 percent lower risk of AF-related problems4
- AdaptivCRT demonstrated a reduction in 30-day hospital readmissions for heart failure of 47 percent5

In the U.S., approximately 5.1 million people suffer from heart failure6 and the estimated cost for treating heart failure is approximately $40 billion per year.7 Worldwide, more than 23 million people suffer from heart failure.8,9 The disease consumes intensive resources during hospitalizations and continues to cause problems following hospital stays, with six month readmission rates of 50 percent10, 11, 12 and mortality rates of approximately 30 percent.13 Repeated heart failure hospitalizations also are associated with increased mortality.

"Medtronic is committed to improving the lives of people with heart failure at every stage of their care, including those who can benefit from cardiac resynchronization therapy," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic. "With the AdaptivCRT algorithm improving patient response to CRT, we see fewer heart failure complications, and fewer burdens imposed on patients and healthcare resources."

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 around the world.

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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