Medtronic News

Medtronic Announces Initial Results of STOP AF Clinical Trial

Safety and Effectiveness Trial Evaluated the Arctic Front(R) Cardiac CryoAblation Catheter System for the Treatment of Paroxysmal Atrial Fibrillation

MINNEAPOLIS & ATLANTA, Mar 15, 2010 (BUSINESS WIRE) -- Medtronic, Inc. (NYSE:MDT) today announced data from the STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) clinical trial during late-breaking sessions at the 59th Annual Scientific Session of the American College of Cardiology in Atlanta. The data showed superiority over anti-arrhythmic drugs, with 69.9 percent of patients with paroxysmal atrial fibrillation (PAF) treated with the Arctic Front(R) Cardiac CryoAblation Catheter System remaining free of atrial fibrillation (AF) one year after cryoablation, compared to 7.3 percent on drug therapy. All primary safety and effectiveness endpoints in the trial were met. The Arctic Front(R) Cardiac CryoAblation Catheter System is commercially available for use in Europe and certain other countries outside the United States and is under investigational use in the United States.

"These data are a promising indication of the safety profile of cryoablation and its effectiveness in isolating the pulmonary veins to stop AF," said Kevin Wheelan, M.D., chief of staff at Baylor Heart and Vascular in Dallas and investigator with the STOP AF trial. "The cryoballoon demonstrated strong results in treating PAF patients who had previously failed drug treatment."

About STOP AF

As presented at ACC.10 by Douglas Packer, M.D., professor of Medicine, Mayo Clinic in Rochester, Minn. and principal investigator, the STOP AF pivotal clinical trial studied the safety and effectiveness of the Medtronic Arctic Front Cardiac CryoAblation Catheter System in paroxysmal AF patients as compared to drug therapy. Patients were randomized to receive either cryoablation or anti-arrhythmic drug therapy. For every three patients enrolled, approximately two received an ablation and one was randomly assigned to the drug therapy group. Twenty-six U.S. and Canadian centers enrolled 245 patients (163 cryoablation and 82 anti-arrhythmic drugs). Outcomes on all patients were assessed through 12-months of follow-up. These results are part of the PMA submission in consideration for U.S. Food and Drug Administration (FDA) approval for the Medtronic Arctic Front Cardiac CryoAblation Catheter System.

The primary effectiveness outcome was treatment success and was defined as having both acute procedural success and freedom from chronic treatment failure for those patients randomized to cryoablation. Acute procedural success was defined as demonstration of electrical isolation in three or more pulmonary veins at the conclusion of the first cryoablation procedure. Using this definition, acute procedural success was achieved in 98.2 percent (160/163) of cryoablation patients. Chronic treatment failure was defined as the occurrence of detectable AF after a 90-day blanking period (the time after treatment when an AF event is not counted). Chronic treatment failure also included the occurrence of an AF intervention or the use of a non-protocol AF drug anytime during the 12-month follow up. At 12 months, 69.9 percent of cryoablation patients demonstrated treatment success compared to 7.3 percent of anti-arrhythmic drug patients.

The two primary safety outcome measures were Cryoablation Procedure Events (CPEs) in cryoablation subjects and Major Atrial Fibrillation Events (MAFEs) in both study groups. The data indicate that both primary safety outcomes were met. Cryoablation patients with one or more CPE(s) was 3.1 percent with a one-sided 95 percent upper confidence bound of 6.3 percent, which was significantly less than the 14.8 percent pre-specified upper confidence bound ($p < 0.001$). No treatment-related deaths or atrioesophageal fistulas (bleeding between the esophagus and atrium) were reported. In addition, 96.9 percent of cryoablation patients were free from MAFE(s), compared to 91.5 percent of anti-arrhythmic drug patients ($p < 0.001$, non-inferiority).

The trial also captured safety data on several of the more common complications of any ablation procedure in 228 patients that underwent cryoablation procedures including those randomized to cryoablation (163) and those who crossed over for cryoablation (65) after failing drug therapy. Phrenic nerve palsy, a recognized observation with this technology, was noted after 11.2 percent of all cryoablation procedures (29/259) in 228 patients. At 12 months, 224 of the 228 patients (98.2 percent) that received a cryoablation were free of any effects related to phrenic nerve injury. In other safety findings, seven patients (3.1 percent) developed pulmonary vein (PV) stenosis; only two required treatment. Across clinical trials there is considerable variation in the definition and calculation of pulmonary vein stenosis. In STOP AF, PV stenosis was defined as a reduction in the calculated pulmonary vein cross-sectional area to less than 25 percent of the baseline pulmonary vein cross-sectional area. A vein that was stenotic at anytime during study follow-up was considered stenotic for this analysis.

About the Medtronic Arctic Front Cardiac CryoAblation Catheter System

The Medtronic Arctic Front Cardiac CryoAblation Catheter System is designed to be used with fluoroscopy and does not require the use of complex, three-dimensional electroanatomical mapping systems. The technologies used in the STOP AF trial include:

- The Arctic Front Cryocatheter, which inflates and fills with coolant to ablate the tissue where the pulmonary veins enter the left atrium;
- The FlexCath(R) Steerable Sheath, which helps deliver and position the cryocatheter in the left atrium;
- The Freezor(R) *MAX* Cardiac CryoAblation Catheter, which is a single-point catheter used to provide additional ablations, as needed; and
- The CryoConsole, which houses the coolant, electrical and mechanical components that run the catheters during a cryoablation procedure.

A catheter ablation is a minimally invasive procedure that aims to stop the rapid beating of the upper heart chambers by ablating, or blocking, the conduction of AF, including where the pulmonary veins enter the left atrium. The Arctic Front Cardiac CryoAblation Catheter System uses cryoablation, or freezing technology. A coolant is released into the catheter's balloon to freeze and ablate the tissue; freezing helps the balloon maintain contact with the tissue. To date, more than 9,000 patients have been treated worldwide with the Arctic Front cryocatheter.

Caution: The Medtronic Arctic Front Cardiac CryoAblation Catheter System is investigational and not currently available for sale in the United States.The device is limited by federal law to investigational use only.

About Atrial Fibrillation

Atrial fibrillation is an irregular quivering or rapid heart rhythm in the upper chambers (atria) of the heart. Paroxysmal AF occurs when the irregular rhythm starts and stops suddenly on its own. Half of all diagnosed AF patients fail drug therapy. Untreated AF patients have a five times higher risk of stroke.[2] Atrial fibrillation causes inefficient pumping of the heart and can lead to other rhythm problems as well as chronic fatigue, difficulty breathing and heart failure. AF is the most common heart arrhythmia affecting more than 3 million Americans and 7 million people worldwide.[3]

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.

JAMA 2001; 285:2370-5.

[2] Fuster et al. *Journal of the American College of Cardiology.* 2006; 48:854-906.

[3] Millennium Research Report; "Global Markets For Atrial Fibrillation Treatment Devices 2008," March 2008; 1.

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