Medtronic News

Medtronic Announces New Data from STOP AF Pivotal Trial

Trial Demonstrates Significant Decrease in Symptoms and Improved Quality of Life for AF Patients Treated with Arctic Front(R) Cardiac CryoAblation Catheter

MINNEAPOLIS & DENVER, May 14, 2010 (BUSINESS WIRE) --Medtronic, Inc. (NYSE: MDT) today released new STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) clinical trial data showing the number of paroxysmal atrial fibrillation (AF) patients reporting AF symptoms declined by 80 percent after treatment with the Arctic Front(R) Cardiac CryoAblation Catheter System. Additionally, as reported in the quality-of-life questionnaire (SF-36) results, all patients randomized and treated with the Arctic FrontCardiac CryoAblation Catheter System reported significant improvements in physical and mental quality-of-life factors when compared to baseline measurements ($P<0.001$). These data were presented as a late breaking clinical trial at Heart Rhythm 2010, the Heart Rhythm Society's 31st Annual Scientific Sessions. The CryoAblation System is commercially available for use in Europe; it is under investigational use in the United States.

"The significant reduction in AF-related symptoms observed in this trial demonstrates the potential relief that cryoablation therapy can provide to patients suffering from symptomatic paroxysmal AF," said Jeremy Ruskin, M.D., chair of the STOP AF trial steering committee, Director of Cardiac Arrhythmia Service at Massachusetts General Hospital and Associate Professor of Medicine at Harvard Medical School in Boston.

The number of patients randomized to cryoablation in the STOP AF trial who reported AF symptoms declined from 100 percent at baseline (pre-treatment) to 20 percent at 12 months after cryoablation treatment. Specifically, when compared at baseline and 12 months, there was a reduction in the number of study participants who reported the following six symptom categories: palpitations (86 to 25 percent), fatigue (76 to 13 percent), rapid heart beat (66 to 16 percent), dyspnea, or difficulty breathing (54 to 9 percent), dizziness (48 to 9 percent), and syncope, or fainting (4 to 1 percent). To some AF patients, these symptoms can be debilitating.

About STOP AF

The STOP AF pivotal clinical trial enrolled 245 patients at 26 U.S. and Canada centers and studied the safety and effectiveness of the Medtronic Arctic Front Cardiac CryoAblation Catheter System in paroxysmal AF patients as compared to drug therapy. All primary safety and effectiveness endpoints in the trial were met. These results are part of the PMA submission under regulatory review by the U.S. Food and Drug Administration (FDA) approval for the CryoAblation System.

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 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. To treat AF, the goal is 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 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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