Medtronic News

Medtronic Announces Results from TTOP-AF Trial Demonstrating Clinical Benefits of Its Phased RF Ablation System in Treating Persistent Atrial Fibrillation

First Ever Randomized, Controlled Clinical Trial in Persistent Atrial Fibrillation (AF) Patients

VENICE, Italy & MINNEAPOLIS, Oct 10, 2011 (BUSINESS WIRE) --

Medtronic, Inc.(NYSE: MDT) today announced results from its Tailored Treatment of Permanent Atrial Fibrillation (TTOP-AF) clinical trial, the first randomized study comparing ablation therapy with the Medtronic Phased RF Ablation System ablation system to traditional medical management (antiarrhythmic drugs and direct current cardioversion) in 210 patients with persistent or long-standing persistent atrial fibrillation (AF). The findings, presented today at Venice Arrhythmias 2011, the 12th International Workshop on Cardiac Arrhythmias, demonstrated that 55.8 percent of ablation management patients had an AF and atrial flutter burden reduction of greater than 90 percent and were free of antiarrhythmic drug therapy at six months compared to 26.4 percent in the traditional medical management arm ($p<0.0001$), thus meeting the chronic effectiveness endpoint. When including patients still on antiarrhythmic drug therapy following the procedure with the ablation system, 67.4 percent had a greater than 90 percent reduction of AF burden at six months.

While the ablation patients in the trial demonstrated a reduction in AF burden, the acute safety event rate in the trial was 12.3 percent with an upper 95 percent confidence interval of 19 percent, which did not meet the pre-defined performance goal of 16 percent. At the time the trial was designed, no benchmark for the persistent AF patient population existed, so the performance goal of 16 percent was established based on a literature review evaluating ablation procedures for right-sided and paroxysmal AF ablation procedures. In the TTOP-AF trial, 12.3 percent (17) of patients experienced one or more protocol-defined procedural and/or device-related adverse events within 7 days of the procedure. A total of 4 strokes (1.7 percent acute procedural stroke rate) occurred within the acute period after an ablation procedure. The stroke incidence was higher for the first few subjects undergoing an ablation procedure rather than for subjects enrolled later at each site, with 3 of the 4 strokes occurring during the first 5 procedures for each clinical trial center. Two of the 4 patients had complete resolution of symptoms within the 6-month follow-up period; the other 2 patients had minor residual effects from the stroke.

"Due to the advanced state of the disease and the attendant increase in the complexity of the procedure, persistent AF patients undergoing ablation have a higher risk than paroxysmal AF patients for adverse events; therefore, the acute safety findings from the TTOP-AF trial are not unexpected," said John Hummel, M.D., director of clinical electrophysiology research at The Ohio State Medical Center. "I believe these data are promising given the reduction in AF burden, and therefore this ablation technology may ultimately represent an important option for drug refractory, symptomatic, persistent AF patients who are more difficult to treat."

There is a significant unmet need for U.S. patients with symptomatic, drug refractory persistent AF. The only FDA approved AF ablation therapies are indicated for the treatment of paroxysmal AF, which is a type of AF in which irregular heartbeats in the upper chambers start and stop suddenly on their own, usually for minutes or days at a time. As the disease progresses into persistent AF (recurrent AF episodes that last more than 7 days), it becomes more complex to treat. Persistent AF patients often have increased hospitalizations and healthcare costs, and the condition is more debilitating for the patients in terms of quality of life. Additionally, persistent AF often causes structural, functional and electrical changes to the heart.

"Medtronic is fully committed to developing the most clinically advanced medical technologies to treat the millions of patients who suffer from atrial fibrillation, a condition that costs the healthcare system billions of dollars each year," said Reggie Groves, vice president and general manager of Medtronic's AF Solutions business. "We believe these data demonstrate the Medtronic Phased RF Ablation System can fill an unmet need for persistent AF patients who have few treatment options with significant

limitations."

About the TTOP-AF Clinical Trial

The prospective multi-center, controlled clinical trial - the largest to date to study the phased radiofrequency ablation technology - included a total of 210 patients with persistent and long-standing persistent AF who were randomized in a 2:1 fashion to either receive ablation treatment (138) or traditional medical management (72). Medical management treatment failures were permitted to crossover and receive an ablation, no sooner than 4 months after enrollment with a target of 6 months. Twenty three sites participated in the United States and one in the Netherlands. Patients in the ablation arm were allowed up to two ablations with Medtronic's Phased RF Ablation System to achieve treatment success, and were followed at 1, 3 and 6-months post-treatment. Patients in the medical management arm received antiarrhythmic drug changes and direct current cardioversions to achieve and maintain sinus rhythm, and were followed at 1, 3 and 6-months.

About the Medtronic Phased RF Ablation System

The Medtronic Phased RF Ablation System is investigational in the United States and currently approved for use in regions of Europe, Asia, and Africa, as well as in Canada. The system is a percutaneous cardiac catheter and generator system that delivers customized radiofrequency (RF) energy designed to eliminate or isolate abnormal electrical impulses in the left atrium (upper left chamber of the heart) that initiate or sustain atrial fibrillation. The anatomically designed, multi-electrode catheters are intended to allow physicians to identify and selectively ablate a broader area of heart tissue without the use of current single point catheters and complex mapping and navigation equipment.

The Medtronic Phased RF Ablation System includes:

- Pulmonary Vein Ablation Catheter (PVAC)(TM) - designed for mapping, ablating and verifying isolation of the pulmonary veins;
- Multi-Array Septal Catheter (MASC)(TM) - designed for mapping and ablating the left atrial septal wall;
- Multi-Array Ablation Catheter (MAAC)(TM) - designed for mapping and ablating the left atrial body; and
- GENius Multi-Channel Radiofrequency Generator - the unique RF energy delivery system allows physicians to tailor the location, depth and fill of each ablation lesion.

More than 13,000 patients in 24 countries have been treated with the Medtronic Phased RF Ablation System since January 2009.

About Atrial Fibrillation

Atrial fibrillation (AF or A Fib) is an irregular quivering or rapid heart rhythm in the upper chambers (atria) of the heart. AF is the most common cardiac rhythm condition, found in approximately three million Americans and seven million people worldwide.Untreated AF patients have a two- to seven-times higher risk of stroke. Persistent AF patients typically have more risk factors for stroke, including advanced age, hypertension, and diabetes. Atrial fibrillation causes inefficient pumping of the heart and can lead to chronic fatigue and congestive heart failure. Half of AF patients who receive treatment are non-responsive to drug therapy, making them potential candidates for ablation therapy.

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.

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