Medtronic News

FDA Advisory Panel Makes Recommendation on Investigational Medtronic Phased RF Ablation System for Treatment of Persistent or Long-Standing Persistent Atrial Fibrillation

MINNEAPOLIS, Oct 27, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced that the U.S. Food and Drug Administration's (FDA) Circulatory Systems Devices advisory panel voted against the Medtronic Phased RF Ablation System, the first atrial fibrillation ablation therapy under investigation for the treatment of persistent and long-standing persistent atrial fibrillation. While the panel unanimously agreed the technology is effective, the majority did not believe there is reasonable assurance of the safety of the Medtronic Phased RF Ablation System, and that the clinical benefits of the technology do not outweigh the potential risks based on the TTOP-AF clinical trial data.

Today's committee recommendation, although not binding, will be considered by the FDA as it reviews the pre-market approval application for the Medtronic Phased RF Ablation System. Medtronic submitted a modular pre-market approval (PMA) application with the last submission completed in June 2011 based on data from its pivotal TTOP-AF (Tailored Treatment of Persistent Atrial Fibrillation) clinical trial, the first randomized study comparing ablation therapy to traditional medical management (antiarrhythmic drugs and direct current cardioversion) in patients with persistent or long-standing persistent atrial fibrillation.

"While we are disappointed with today's outcome, Medtronic looks forward to continuing discussions with the FDA to determine the best path forward," said Reggie Groves, vice president and general manager of Medtronic's AF Solutions business. "We believe this technology would represent an important option for the persistent or long-standing persistent atrial fibrillation population, for whom treatment is limited."

Currently, the only FDA approved atrial fibrillation ablation medical devices are indicated for the treatment of paroxysmal atrial fibrillation, a type of disease 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 (recurrent episodes that last more than 7 days) or long-standing persistent (continuous episodes that last more than one year) atrial fibrillation, it becomes more complex to treat. Persistent atrial fibrillation patients often have increased hospitalizations and healthcare costs, and the condition is more debilitating in terms of quality of life.

Results from the TTOP-AF clinical trial were presented on October 10, 2011 at Venice Arrhythmias 2011, the 12th International Workshop on Cardiac Arrhythmias. The study met its chronic effectiveness endpoint, demonstrating that 55.8 percent of patients treated with the Medtronic Phased RF Ablation System had an atrial fibrillation and atrial flutter burden reduction of greater than 90 percent and were free from antiarrhythmic drug therapy at six months, compared to 26.4 percent in the traditional medical management arm ($p<0.0001$). 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 atrial fibrillation burden at six months.

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 atrial fibrillation patient population existed, so the performance goal of 16 percent was established based on a literature review evaluating ablation procedures in paroxysmal atrial fibrillation ablation patients. These specific safety findings were not unexpected since persistent or long-standing persistent atrial fibrillation patients undergoing ablation have a higher risk of adverse events due to the advanced state of the disease and the complexity of the procedure.

The Medtronic Phased RF Ablation System is investigational in the United States and currently approved for use in areas of Europe, Asia, and Africa, as well as in Canada. More than 13,000 patients in 24 countries have been treated with the system since January 2009.

About the Medtronic Phased RF Ablation System

The Medtronic Phased RF Ablation 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.

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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Medtronic, Inc.
Wendy Dougherty, 763-526-2853
Public Relations
Jeff Warren, 763-505-2696
Investor Relations

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