Medtronic News

First Patient Enrolled in Medtronic-Supported Head-to-Head Clinical Trial Comparing Cryoballoon Ablation to RF Ablation for Paroxysmal Atrial Fibrillation

MINNEAPOLIS--(BUSINESS WIRE)--Jan. 24, 2012-- Medtronic, Inc. (NYSE: MDT) today announced the first patient was enrolled in the FIRE AND ICE clinical trial, which is a prospective, randomized, multinational head-to-head clinical trial comparing the long-term safety, effectiveness and ease of use of the Medtronic Arctic Front® Cardiac CryoAblation System compared to the Biosense Webster CARTO® System Guided THERMOCOOL® Catheter to treat patients with symptomatic paroxysmal atrial fibrillation. Results from the trial, expected in 2014, could potentially impact atrial fibrillation treatment guidelines by providing further clinical evidence regarding the benefits of the Arctic Front system in treating a largely underserved patient population.

“Through this rigorously designed study, we hope to further validate the long-term treatment benefits associated with cryoballoon ablation,” said Karl-Heinz Kuck, M.D., principal investigator and director of cardiology, at Asklepios Klinik St. Georg, Hamburg, Germany. “Given the Arctic Front system’s clinically robust safety and efficacy profile, combined with its straightforward simplicity, this innovative medical technology has the potential to become the standard of care in treating paroxysmal atrial fibrillation.”

The largest clinical study to date to compare two atrial fibrillation ablation devices, the FIRE AND ICE trial will enroll up to 572 patients from up to 20 medical centers throughout Europe. Patients participating in the study must be diagnosed with symptomatic paroxysmal atrial fibrillation and must have failed at least one antiarrhythmic drug. Participants will be followed for an average of one year after initial ablation. The primary endpoint of the trial is the absence of atrial arrhythmias without antiarrhythmic drug therapy and without persistent procedure-related serious adverse events such as strokes, pulmonary vein stenosis and phrenic nerve injury at six and 12 months following ablation. Key secondary endpoints that will be assessed include procedural data (total procedure duration, time of fluoroscopy and duration of hospital stay), quality of life, sedation and the need for atrial flutter ablation.

The numerous short- and long-term benefits of the Arctic Front system have been well established via numerous studies, as well as in the clinical setting, with more than 20,000 successful procedures conducted to date. According to data from the pivotal STOP AF (Sustained Treatment of Paroxysmal Atrial Fibrillation) trial, on which the FDA approval of the Arctic Front Cardiac CryoAblation System was based, 69.9 percent of patients treated with the innovative technology were free from atrial fibrillation at one year, compared to 7.3 percent of patients treated with drug therapy only. Patients enrolled in the study displayed a significant reduction of symptoms, a decrease in the use of anti-arrhythmic drug therapy and substantial improvements in both physical and mental quality of life factors. The study also demonstrated that treatment with the device is safe, with limited serious procedure-related adverse events (3.1 percent).

“Medtronic is committed to building upon a strong foundation of scientific evidence to help inform physicians’ clinical decisions and help them select technologies that are best suited for their individual patients,” said Reggie Groves, vice president and general manager of Medtronic’s AF Solutions business. “We look forward to further confirming – via this large-scale, multicenter trial – that our novel cryoballoon ablation technology offers a compelling alternative to radiofrequency ablation.”

To treat atrial fibrillation, the goal of minimally-invasive catheter ablation therapy is to isolate the pulmonary veins by blocking the conduction of electrical signals that trigger erratic heart rhythms in the upper heart

chambers. The Arctic Front cryoballoon system freezes and blocks these erratic triggers, while conventional ablation therapy uses radiofrequency energy with a point-by-point catheter to isolate the triggers by heating. The freezing helps the balloon maintain contact with the heart tissue during the procedure, allowing for greater catheter stability. A leading advancement from currently available ablation tools, cryoablation has been shown to be faster for physicians to use than a point-by-point catheter, and it has been proven more effective than anti-arrhythmic drug therapy in treating patients with paroxysmal atrial fibrillation.

About the Arctic Front Cardiac CryoAblation Catheter System

The 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 offered in the system include:

- The Arctic Front Cryoballoon, which inflates and fills with coolant to ablate the tissue where the pulmonary veins enter the left atrium;
- The FlexCath® Steerable Sheath, which helps deliver and position the cryocatheter in the left atrium;
- The Achieve™ Mapping Catheter, an intra-cardiac electrophysiology recording catheter used to assess pulmonary vein isolation when treating paroxysmal atrial fibrillation.
- The Freezor® 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.

About Atrial Fibrillation

Atrial fibrillation is the most common and one of the most undertreated heart rhythm disorders, affecting more than 7 million people worldwide. It is estimated that half of all diagnosed atrial fibrillation patients fail drug therapy, and if left untreated patients have up to a five times higher risk of stroke and an increased chance of developing heart failure. Additionally, since atrial fibrillation is often age-related, as the global population continues to grow older, the need for more effective treatment options is escalating.

Paroxysmal atrial fibrillation is a type of atrial fibrillation in which irregular heartbeats in the upper chambers start and stop suddenly on their own, usually for minutes or days at a time.

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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