Medtronic News

Medtronic Begins VICTORY AF Trial of Patients with Persistent or Long-Standing Persistent Atrial Fibrillation

MINNEAPOLIS - Jan. 6, 2014 - Medtronic, Inc. (NYSE:MDT) today announced the first patient has been enrolled in the VICTORY AF clinical trial, a prospective, non-randomized, controlled study of patients with persistent or long-standing persistent atrial fibrillation (AF) undergoing an ablation procedure with Medtronic's Phased Radiofrequency (RF) system. The study will evaluate the safety of this system, while collecting additional effectiveness data. The Medtronic Phased RF System is investigational in the United States.

"In strong collaboration with the FDA, we designed the VICTORY AF trial to evaluate the safety of Phased RF ablation in patients who suffer with persistent or long-standing persistent AF," said Reggie Groves, vice president and general manager of the AF Solutions division at Medtronic. "We expect this trial will demonstrate its safety and benefit for this patient population."

Forty centers throughout the United States, Canada and Europe will participate in VICTORY AF (Evaluation of Multielectrode Phased RF Technology in Persistent AF), which will enroll up to 350 symptomatic patients with persistent or long-standing persistent AF for whom medication has not been effective. The primary study objective is to establish the 30-day procedure-related stroke rate and/or device-related stroke rate as <=1.8 percent. Secondary objectives include six-month effectiveness, rates of pulmonary vein stenosis, and acute procedural success. The principal investigator is Greg Michaud, M.D., assistant professor, Harvard Medical School, and director, Center for the Advanced Management of Atrial Fibrillation at Brigham and Women's Hospital in Boston. The first patient in this study was recently treated by Dr. David DeLurgio of Emory University Hospital Midtown in Atlanta.

Persistent AF is defined as sustained AF lasting more than seven days but less than one year, or lasting fewer than seven days but requiring cardioversion through medication or electrical current. Long-standing persistent AF is defined as continuous AF lasting more than one year but fewer than four years.

In the United States, AF ablation catheters currently are available only for treating the mildest form of AF (paroxysmal AF) in which the heart's upper chambers beat rapidly and irregularly during episodes lasting from a few minutes to a few days. AF can progress into a persistent or long-standing persistent state, where patients are often drug refractory, meaning that there is no effective medication to treat the condition. Patients with persistent and long-standing persistent AF can have debilitating symptoms and are at elevated risk for stroke, hospitalizations and reduced quality of life.

The Medtronic Phased RF System is currently approved for use in areas of Europe, Asia, Africa, Australia, and Canada. More than 20,000 patients in 26 countries have been treated with this system since January 2009.

About the VICTORY AF trial

The VICTORY-AF trial is a follow-up to the TTOP-AF (Tailored Treatment of Permanent Atrial Fibrillation) study, which was the first randomized clinical trial to compare the Medtronic Phased RF System to conventional medical management of AF (antiarrhythmic drug therapy and direct-current cardioversion). The TTOP-AF data showed that 55.8 percent of ablation patients had more than a 90 percent reduction in AF/atrial flutter burden and were free of antiarrhythmic drug therapy at six months [significantly more than the 26.4 percent of such patients in the medical management group ($p<0.0001$)]. An FDA Advisory Panel agreed the system was effective, but since it did not meet the pre-specified safety endpoint, the panel encouraged Medtronic to collect additional clinical data on the Phased RF system, which will be done through VICTORY AF.

About the Medtronic Phased RF System

The Medtronic Phased RF System consists of a generator and endocardial catheters. The system delivers customized RF energy designed to eliminate or block abnormal electrical impulses in the left atrium that initiate or sustain AF. The anatomically

designed, multi-electrode catheters are intended to allow physicians to identify and selectively ablate a broad area of heart tissue without the need for single-point catheters or complex mapping and navigation equipment.
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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