Medtronic-Sponsored European Clinical Trial to Evaluate Cryoballoon Ablation as First-Line Treatment for Patients with Symptomatic Paroxysmal Atrial Fibrillation

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MINNEAPOLIS - Jan. 8, 2015 - Medtronic, Inc., (NYSE:MDT) today announced the initiation of a randomized clinical trial in Europe to assess the benefits of ablation using the Medtronic Arctic Front Advance(TM) cryoballoon as a first-line treatment for atrial fibrillation (AF) patients. While medication is currently considered first-line treatment for AF, clinical research indicates that half of all patients with symptomatic disease do not respond to drug therapy[1]; earlier ablation may improve treatment effectiveness.

The Cryo-FIRST (Catheter Cryoablation Versus Antiarrhythmic Drug as First-Line Therapy of Paroxysmal Atrial Fibrillation) trial will evaluate the procedural success and clinical outcomes of patients with paroxysmal AF (PAF) undergoing cryoballoon ablation as an initial treatment compared with medication. It will include approximately 218 patients in up to 12 centers across Europe; enrollments have occurred at Heart Rhythm Management Centre, UZ Brussel-VUB Brussel (Brussels, Belgium); Clinique Saint Gatien (Tours, France); CHU d' Amiens (Amien, France) and Kerckhoff-Klinik (Bad Nauheim, Germany).

The most recent European guidelines highlight that ablation should be considered as first-line therapy in selected patients with symptomatic PAF[2]. Cryoballoon ablation is not approved as a first-line treatment in the U.S.

Approximately 7 million people worldwidecurrently suffer from AF[3], an irregular quivering or rapid heart rhythm in the upper chambers of the heart that is associated with increased morbidity and mortality as well as added healthcare costs. Cryoablation involves a minimally invasive procedure that creates lesions by freezing tissue in the heart's upper chambers, traditionally around the pulmonary veins, to block the electrical signals that trigger erratic heart rhythms. Pulmonary vein isolation (PVI) is a standard treatment for patients in the early stages of AF when the triggers come largely from these veins. However, as the disease progresses, it becomes more complicated to treat, with lower long-term success rates.

"For select patients with symptomatic paroxysmal AF and minimal or no heart disease, this therapy - with its established safety profile - has potential as a first-line treatment, providing valuable clinical insights and evidence for future therapeutic solutions," said Dr. Heinz-Friedrich Pitschner, M.D., Kerckhoff-Klinik Heart Center, and chair of the Cryo-FIRST Steering Committee.

"With the prevalence of AF expected to increase exponentially over the next generation, we believe that cryoballoon ablation therapy may safely and effectively address the disease before it progresses, improving outcomes and quality of life for patients, and reducing healthcare costs," said Reggie Groves, vice president and general manager of Medtronic's AF Solutions business.

About the Cryo-FIRST Trial
The Cryo-FIRST trial is led by principal investigators Dr. Malte Kuniss of the Kerckhoff-Klinik Heart Center, and Dr. Gian Battista Chierchia, of the Heart Rhythm Management Centre, UZ Brussel-VUB. It is a multicenter, prospective, randomized study designed to assess the procedural feasibility and clinical outcomes of patients undergoing cryoballoon ablation as a first-line treatment for PAF as compared to antiarrhythmic drugs.

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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[1]Wilber DJ, Pappone C, Neuzil P, et al. Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: a randomized controlled trial. JAMA; 303: 333-40.
[2] Corrigendum to: 'Guidelines: 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC Guidelines for the management of atrial fibrillation.' Eur Heart J (2012) 33 (21): 2719-2747; doi:10.1093/eurheartj/ehs253
[3] Millennium Research Report; "Global Markets For Atrial Fibrillation Treatment Devices 2008," March 2008; 1.

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