Medtronic News

Medtronic Cryoablation Superior to Drug Therapy for Symptomatic Paroxysmal Atrial Fibrillation

ESC Congress: New Research Highlights First-Line Use of Cryoablation as Highly Effective, and with Improved Quality of Life Scores

DUBLIN, Aug. 29, 2020 (GLOBE NEWSWIRE) --Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced clinical trial results demonstrating superiority of the Arctic Front™ Advance Cardiac Cryoballoon and Freezor® MAX Cardiac CryoAblation Catheter for the first-line treatment (prior to drug therapy) of recurrent symptomatic paroxysmal atrial fibrillation (PAF) compared to antiarrhythmic drug (AAD) treatment. Primary results of the randomized STOP AF First trial were presented as a late breaking clinical trial at the European Society of Cardiology (ESC) Congress 2020 Digital Experience. Additionally, 12-month outcomes from the Cryo-FIRST trial showed a significant improvement in atrial fibrillation-related quality of life with the use of the Medtronic cryoablation system compared to anti-arrhythmic drug therapy in patients who had not previously received antiarrhythmic drugs to treat their symptomatic PAF.

Atrial fibrillation (AF) is a progressive condition that impacts more than 33 million people worldwide[1] Without early intervention, progression of the condition is associated with a higher rate of cardiovascular admissions,[2] heart failure hospitalization,[3] and mortality,[4] along with a reduced quality of life.[5] Antiarrhythmic drug therapy is currently the standard first-line treatment for patients with AF; however, AF recurs in approximately 50% of patients treated with AADs within a year of therapy onset. In addition, AAD therapy frequently causes side effects that can lead many patients to discontinue treatment.[6] Cryoablation uses cold energy (freezing) delivered through an inflatable balloon to create scar tissue to interrupt unwanted electrical pathways in the heart.

STOP-AF First Primary Results

The STOP-AF First trial enrolled 225 patients at 24 sites in the United States and was designed to evaluate the safety and effectiveness of the Medtronic cryoablation system to treat recurrent symptomatic PAF in patients who had not previously received antiarrhythmic drugs for their AF. A total of 203 patients randomized to cryoablation (104 in treatment arm) or AAD therapy (99 in control arm) received treatment and were followed for 12 months.

Results showed superiority of cryoablation for maintaining freedom from AF, atrial tachycardia and atrial flutter, with treatment success achieved in 75% of patients in the catheter ablation group versus 45% in the AAD group ($P<0.0001$). Furthermore, the trial revealed a low rate of safety events with catheter ablation as a first-line therapy (1.9%). Previous studies have consistently demonstrated a low rate of serious complications with cryoablation in drug refractory patients; the STOP AF First study furthers these observations specifically to patients who had not previously received antiarrhythmic drugs to treat their symptomatic PAF.[7,8]

Cryo-FIRST Quality of Life Results

Cryo-FIRST was a randomized, multicenter trial that enrolled 220 patients at 18 sites in nine countries across Europe, Australia and Latin America. Similar to STOP AF First, this trial found that the Medtronic cryoablation system is superior to AAD therapy for the prevention of atrial arrhythmia recurrence in PAF patients who have not previously been treated with drug therapy.

New quality of life findings from the trial, also presented at ESC 2020, showed the Medtronic cryoablation solution resulted in a significant improvement in AF-specific, health-related quality of life at 12 months compared to AAD therapy.

“More than half of patients with symptomatic AF do not experience a reduction in AF with antiarrhythmic drugs, effectively delaying their therapy and leaving a critical need for an alternative first-line treatment,” said Rob Kowal, M.D., Ph.D., chief

medical officer of the Cardiac Rhythm and Heart Failure and the Cardiac Ablation Solutions divisions, which are part of the Cardiac and Vascular Group at Medtronic. “Not only do the STOP AF First findings show cryoablation is a potential first-line treatment for these patients, the Cryo-FIRST results show encouraging benefits of this treatment approach on these patients’ quality of life.”

The Arctic Front Advance Cryoablation System is approved in Europe for the treatment of AF. The United States Food and Drug Administration (FDA) recently expanded the indication for Medtronic cryoablation therapy to include treating patients with symptomatic, recurrent persistent AF, in addition to patients with drug refractory, recurrent, symptomatic paroxysmal AF. Results of the STOP-AF First trial have not been reviewed by the FDA.

“The strong evidence from these trials will help bring cryoablation treatment to more patients suffering from AF earlier in the course of their disease,” said Rebecca Seidel, vice president and general manager of Cardiac Ablation Solutions. “Medtronic has very robust clinical evidence supporting the Arctic Front Family of Cardiac Catheters as a first line therapy for paroxysmal AF, and for paroxysmal and persistent AF patients whose condition is unresponsive to drug 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. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world’s largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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] Chugh S, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a global burden of disease 2010 study. *Circulation*. 2014; 129:837-847.

[2] de Vos CB et al. rogression from paroxysmal to persistent atrial fibrillation clinical correlates and prognosis*J Am Coll Cardiol*. 2010;55(8):725-731.

[3] Wong JA et al. Progression of Device-Detected Subclinical Atrial Fibrillation and the Risk of Heart Failure*J Am Coll Cardiol*. 2018;71(23):2603-2611.

[4] Piccini JP et al. Atrial fibrillation burden, progression, and the risk of death: a case-crossover analysis in patients with cardiac implantable electronic devices. *Europace*. 2019;21(3):404-413.

[5] Dudink E et al. The influence of progression of atrial fibrillation on quality of life: a report from the Euro Heart Survey*EP Europace*, Volume 20, Issue 6, June 2018, Pages 929–934

[6] Valembois L et al. Antiarrhythmics for maintaining sinus rhythm after cardioversion of atrial fibrillation.*Cochrane Database of Systematic Reviews* 2019, Issue 9. Art. No.: CD005049. DOI: 10.1002/14651858.CD005049.pub5.

[7] Knight BP, Novak PG, Sangrigoli R, et al.; STOP AF PAS Investigators. Long-Term Outcomes After Ablation for Paroxysmal

Atrial Fibrillation Using the Second-Generation Cryoballoon: Final Results From STOP AF Post-Approval Study. JACC Clin Electrophysiol. 2019; 5(3): 306-314.

[8] Hoffmann E, Straube F, Wegscheider K, et al. Outcomes of cryoballoon or radiofrequency ablation in symptomatic paroxysmal or persistent atrial fibrillation. Europace 2019;21:1313-24.

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