Medtronic News

Medtronic Initiates Global Trial Evaluating Cryoablation to Treat Persistent Atrial Fibrillation

DUBLIN - March 30, 2017 - Medtronic plc (NYSE: MDT) today announced first enrollments in the STOP Persistent AF clinical trial. The trial will evaluate the safety and effectiveness of a pulmonary vein isolation-only (PVI) strategy for treating patients with persistent atrial fibrillation (AF), using the Arctic Front Advance(TM) Cardiac CryoAblation Catheter. John Harding, M.D., Doylestown Hospital in Doylestown, Penn., treated the first patient enrolled in the trial.

STOP Persistent AF is a prospective, multicenter, single-arm clinical trial that will enroll up to 225 patients at 25 centers in the United States, Canada, Europe and Japan. Patients will be followed for 12 months after the initial cryoballoon ablation procedure.

"Gaining meaningful data from this trial will help further clinicians' understanding of possible treatment options for patients with persistent AF," said co-principal investigator Hugh Calkins, M.D., director of the Electrophysiology Laboratory and Arrhythmia Service at the Johns Hopkins Hospital in Baltimore. "As AF progresses and episodes become more constant, patients' quality of life diminishes while their risk of AF-related health effects, such as heart failure and stroke, increases. This trial could help us advance care for this hard-to-treat population."

AF is one of the most common heart rhythm disorders, affecting more than 33 million people worldwide.1 In the United States, AF affects nearly 6.1 million adults, and patients with persistent AF represent approximately a quarter of all AF cases.2,3 Persistent AF occurs when the upper chambers of a patient's heart beat erratically for more than seven days and medical intervention and drug therapy is required to stop the episode. The risk of stroke and heart failure increases in patients with AF.4,5

Recently updated guidelines published by the European Society of Cardiology (ESC) acknowledge cryoablation therapy for AF, and recognize PVI as an effective and preferred treatment option for select patients with AF. The Medtronic cryoballoon has been used in more than 250,000 cases worldwide. Currently, no ablation catheters are approved for treating persistent AF in the United States. The Medtronic Arctic Front Advance(TM) Cryoablation System is approved in the U.S. for the treatment of drug-refractory, recurrent, symptomatic paroxysmal atrial fibrillation and in Europe for the treatment of atrial fibrillation.

"According to a study in *JAMA*, the number of patients with AF is expected to double in the next couple of decades and we want to ensure that physicians are equipped with the most innovative approaches and treatments," said Colleen Fowler, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic. "We hope this study leads to greater insights that can improve care for patients with persistent AF."

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 of the highest quality 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 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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 January C, Wann L, Alpert J, Calkins H, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2014.

3 Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S. Epidemiology of atrial fibrillation: European perspective. Clinical Epidemiology. 2014;6:213-220. doi:10.2147/CLEP.S47385.

4 Fuster et al. Journal of the American College of Cardiology. 2006; 48:854-906.

5 ACC/AHA/ESC Guidelines for the Management of Patients with Atrial Fibrillation

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