Medtronic News

Clinical Trial to Evaluate Medtronic Cryoablation as First-Line Treatment for Patients With Symptomatic Paroxysmal Atrial Fibrillation

DUBLIN - July 11, 2017 - Medtronic plc (NYSE: MDT) today announced first enrollments in the STOP AF First clinical trial. The trial will evaluate the safety and effectiveness of performing pulmonary vein isolation (PVI) with the Arctic Front Advance(TM) Cryoballoon in patients with symptomatic paroxysmal atrial fibrillation (AF) prior to treatment with antiarrhythmic medications. The first patient in the trial was recently enrolled at The Ohio State University Wexner Medical Center by Jaret Tyler, M.D.

STOP AF First is a prospective, interventional, multicenter, randomized, controlled, clinical trial that will enroll up to 210 patients at up to 30 sites in the United States. Patients will be randomized to cryoballoon ablation (treatment arm) or antiarrhythmic drug (AAD) therapy (control arm), and followed for 12 months. Oussama Wazni, M.D., co-director of Atrial Fibrillation Center at Cleveland Clinic, serves as the study's national principal investigator.

"Clinical research shows that about half of patients with symptomatic AF do not respond to antiarrhythmic drugs, leading to recurrence," said Colleen Fowler, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic. "As AF progresses, it becomes more difficult to treat, and has lower long-term success rates. With the number of AF patients expected to increase exponentially in the coming years, this trial will help ascertain whether earlier treatment with the cryoballoon can improve outcomes for a greater number of patients."

Cryoballoon ablation is used in a minimally invasive procedure to isolate the pulmonary veins, which are a source of erratic electrical signals that cause AF. The device uses cold energy (freezing) rather than heat (radiofrequency) to create scar tissue and interrupt irregular electrical pathways in the heart.

The 2016 European Society of Cardiology's (ESC) guidelines and the recent 2017 Heart Rhythm Society (HRS) Consensus Statement for the management of atrial fibrillation both acknowledge cryoablation therapy as an appropriate ablation energy for treating AF, and recognize PVI as an effective and preferred treatment option for select patients with AF.

In the U.S., first-line treatment of symptomatic paroxysmal AF with the Arctic Front Advance Cryoablation System is investigational use only; the system is approved in the U.S. for the treatment of drug refractory, recurrent, symptomatic paroxysmal AF, and in Europe for the treatment of atrial fibrillation. More than 250,000 patients in more than 50 countries worldwide have been treated with the cryoballoon.

More than 33 million people worldwide have AF,1 including nearly 6.1 million adults in the United States,2 a number expected to double in the next 25 years.3 Representing a quarter of all AF patient cases,4 paroxysmal AF occurs when the rapid rhythm in the heart's upper chambers start and stop suddenly, usually for minutes or days at a time.5

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 91,000 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 Go A, Hylek E, Phillips K, et al. Prevalence of Diagnosed Atrial Fibrillation in Adults: National Implications for Rhythm Management and Stroke Prevention: the AnTicoagulation and Risk Factors In Atrial Fibrillation (ATRIA) Study. JAMA. 2001; 285(18): 2370-2375.

4 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.

5 Medtronic, plc. (n.d.). ABOUT ATRIAL FIBRILLATION. Retrieved from http://www.medtronic.com/us-en/patients/conditions/atrial-fibrillation-afib.html.

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