Medtronic News

Study Shows Positive Results with Medtronic Cryoballoon for Patients with Persistent Atrial Fibrillation

DUBLIN and BARCELONA, Spain - MARCH 19, 2018 - Medtronic plc (NYSE: MDT) today announced one-year results from the CRYO4PERSISTENT AF study of ablation with the Arctic Front Advance(TM) Cryoballoon to isolate the pulmonary veins in patients with symptomatic persistent atrial fibrillation (AF). The Arctic Front Advance Cyroablation System is not approved for treating persistent AF in the United States.

The study results, presented today at the European Heart Rhythm Association (EHRA) Scientific Sessions 2018 in Barcelona, Spain, showed 60.7 percent of persistent AF patients were free from all atrial arrhythmias (adjudicated AF, atrial flutter or atrial tachyarrhythmias) lasting more than 30 seconds, at one year following a single ablation procedure. These clinically meaningful results are on par with outcomes seen in the FIRE AND ICE trial of paroxysmal AF patients (approximately 70 percent at 12 months), and are encouraging given these patients are in a more advanced disease state.

The study findings also demonstrated short and predictable procedure times of 53 ±22 minutes with the cryoballoon and a low device- and/or procedure-related complication rate of 4 percent.

"The findings demonstrate the benefits of cryoablation therapy in reducing the significant burden patients experience once AF progresses, and hold promise for physicians to realize efficient procedure times and a low rate of adverse events for their persistent AF patients," said Serge Boveda, M.D., co-director of the Cardiac Arrhythmias Department in Clinique Pasteur, Toulouse, France, and co-principal investigator in the trial. "These results are encouraging and demonstrate the reproducibility of the cryoballoon procedure even in patients with persistent AF."

Medtronic is a world leader in the diagnosis, management and treatment of AF. AF is one of the most common heart rhythm disorders, affecting more than 33 million people worldwide.1 In Europe and the United States, AF affects approximately 10 and 5 million people respectively. In both geographies, persistent AF represents 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 procedural intervention and/or drug therapy are required to stop the episode and restore normal sinus rhythm. Additionally, the risk of stroke and heart failure increases in patients with AF.4,5

"This is the first study of its kind to closely observe patients with persistent AF using a PVI-only strategy with the cryoballoon," said Pascal Defaye, M.D., Arrhythmia Unit, Department of Cardiology, Grenoble-Alpes University Hospital, Grenoble, France, and co-principal investigator in the trial. "The results are noteworthy and provide valuable insights for the physician community."

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 rather than heat (radiofrequency (RF) ablation) to create scar tissue and interrupt irregular electrical pathways in the heart. Recent studies have shown comparable safety and effectiveness when using cryoballoon ablation compared to RF ablation when treating symptomatic paroxysmal AF patients, as well as shorter and more consistent procedure times.6,7

"Similar to what we saw with the FIRE AND ICE clinical trial, the CRYO4PERSISTENT AF findings demonstrate the significant benefits of cryo energy for the treatment of AF," said Rebecca Seidel, vice president and general manager of the AF Solutions business, part of the Cardiac and Vascular Group at Medtronic. "As more and more physicians around the world adopt cryoablation, we are committed to providing the technology and expertise to help them bring better, more efficient care for their patients."

More than 370,000 patients in more than 60 countries worldwide have been treated with the cryoballoon. The Arctic Front

Advance Cryoablation System is approved in Europe for the treatment of AF. In the U.S., the Arctic Front Advance Cryoablation System is approved for the treatment of drug refractory, recurrent, symptomatic paroxysmal AF.

The 2016 European Society of Cardiology's (ESC) guidelines and the 2017 Heart Rhythm Society (HRS) Consensus Statement for the management of AF both acknowledge cryoablation therapy as a reasonable ablation energy for treating AF and recognize PVI as an effective and preferred treatment option for select patients with 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. Medtronic 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 CRYO4PERSISTENT AF

CRYO4PERSISTENT AF is a prospective, single-arm, interventional, multi center, non-randomized clinical trial that evaluated the 12-month clinical outcomes of cryoballoon ablation for isolating pulmonary veins, without additional ablation strategies, using the Medtronic Arctic Front Advance Cryoballoon System to treat patients with persistent AF. Eligible patients were defined as having documented symptomatic persistent AF at baseline lasting longer than 7 days and up to 180 days. Prior to procedure, enrolled patients were monitored using 18-hour Holter recorders to ensure all investigated patients met the 100 percent persistent AF documentation criteria. Per protocol, a total of 101 patients were analyzed and followed for 12 months at 11 medical centers throughout Europe. Co-principal investigators are Dr. Serge Boveda and Dr. Pascal Defaye.

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 84,000 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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2 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.

3 Mozaffarian D, Benjamin EJ, Go AS, et al. Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. Circulation. 2016 Jan 26;133(4):e38-360

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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