Medtronic News

Medtronic Affera™ Mapping and Ablation System with Sphere-9™ Catheter achieves endpoints for safety and efficacy, providing promising evidence for the future of atrial fibrillation treatment

HRS late breaking data: SPHERE Per-AF trial demonstrates novel all-in-one system delivers exceptional results, plus increased efficiency and improved quality of life

DUBLIN and BOSTON, May 17, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced positive results demonstrating excellent safety and efficacy of the Affera™ Mapping and Ablation System with Sphere-9™ Catheter, an all-in-one pulsed field (PF) and radiofrequency (RF) ablation and high density (HD) mapping catheter for the treatment of persistent atrial fibrillation (AFib). The SPHERE Per-AF study, a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) pivotal trial, compared Sphere-9 to the conventional Thermocool SmartTouch® SF radiofrequency ablation catheter with the Carto™ 3 System. Findings were presented as late-breaking clinical data at the Heart Rhythm Society (HRS) 2024 Annual Meeting and simultaneously published in *Nature Medicine*.

"These are excellent results for the investigational Sphere-9 catheter. The data show Sphere-9 lattice tip technology enables physicians to create a wide circumferential pulmonary vein isolation, which is the cornerstone of any type of AFib ablation, and any set of desired ablation lesions, in a safe, effective and efficient manner," said Elad Anter, M.D., Director of the Arrythmia Institute, Shamir Medical Center, Israel. "Persistent AFib patients make up 30-50% of the patient population and are often challenging to treat, with the majority of procedures requiring additional lesion sets beyond pulmonary vein isolation. The versatility and ease of use of this mapping and ablation system led to impressive efficiency and treatment outcomes in the trial."

- The Sphere-9 Catheter demonstrated a **positive safety profile** with an excellent primary safety endpoint rate of 1.4% (1.0% for the control arm). Importantly, no safety events including pulmonary vein stenosis, esophageal events or cardiac tamponade were reported. More than 95% of Sphere-9 procedures used a single transeptal puncture compared to 62% in the control arm.
- Sphere-9 demonstrated **73.8% freedom from AFib*** vs. only 65.8% observed in the control arm. Following 100% acute isolation of pulmonary veins and linear lesions, patients treated with the Sphere-9 Catheter also observed less recurrence of atrial arrhythmias throughout the 12-month follow up period.
- Treatment with the Sphere-9 catheter demonstrated **superior efficiency** over the control arm for procedural characteristics including:
    - Skin-to-skin procedural time
    - Time between first and last ablation
    - Energy application time
- Patients treated with the Sphere-9 catheter experienced **improvements to quality of life** in both mental and physical well-being.

"As pioneers in cardiac ablation treatment, including cryoablation and PFA, we are thrilled to share these results providing excellent evidence for use of this all-in-one catheter that can be used with no need to pull a second catheter," said Rebecca Seidel, president, Cardiac Ablations Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "The Affera Mapping and Ablation system with Sphere-9 Catheter demonstrates a positive safety, efficacy and efficiency profile and can amplify our innovative and trusted portfolio. With these results, we are now one step closer to bringing this technology to the U.S. and beyond."

SPHERE Per-AF was a prospective, multicenter, randomized clinical trial evaluating the Sphere-9 Catheter with the Affera Mapping and Ablation System for treatment of persistent AFib. Subjects were randomized 1:1 to receive treatment with either the Sphere-9 Catheter with the Affera Mapping and Ablation System or the Thermocool SmartTouch® SF radiofrequency

ablation catheter with the Carto™ 3 System. For the primary analysis, a total of 420 patients were enrolled across 23 sites in three countries: the United States, Czech Republic and Israel. All patients in both arms of the trial received pulmonary vein isolation as well as linear lesions based on the patient's needs.

Affera Sphere-9 features include:

- All-in-one HD mapping and ablation catheter fully integrated with the Affera Mapping and Ablation System
- 9mm lattice tip with large footprint
- Convenience of dual energy, pulsed field or radiofrequency

"We've been waiting for one catheter that can be used for every arrhythmia, and these randomized results from centers that routinely use conventional point by point ablation indicate Affera Sphere-9 will be worth the wait with all its innovation and the rapid learning curve of the system," said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. "These are important, highly anticipated results and groundbreaking news for the electrophysiology community that could change the treatment workflow."

The company recently filed for approval of the Affera Sphere-9 Catheter in the U.S. with the FDA. The Affera Sphere-9 Catheter is investigational in the United States and not approved for sale or distribution. The Affera Mapping and Ablation System, which includes the Sphere-9 Catheter, received CE Mark approval in March 2023.

AFib is one of the most common and undertreated heart rhythm disorders, affecting more than 60 million people worldwide[1]. Afib is a progressive disease, often beginning as paroxsymal AFib (presents intermittently) and progressing to persistent (lasts for more than 7+ days without stopping). As the disease progresses, the risk of serious complications including heart failure, stroke and risk of death increases[2-5].

For more information on Affera SPHERE-9, visit Medtronic.com.

*The primary effectiveness endpoint was a composite of freedom from: failure to isolate all targeted pulmonary veins and complete all left atrial ablation with the assigned study device; repeat ablation at any time after the index procedure; and after a 3-month blanking period, documented occurrence of atrial tachyarrhythmia, escalation or initiation of Class I or III antiarrhythmic drugs, or cardioversion.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin,Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow Medtronic on LinkedIn.

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.

Thermocool SmartTouch and Carto are trademarks of Biosense Webster, Inc.

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