Medtronic News

Medtronic Affera™ pulsed field ablation technologies continue to demonstrate promising evidence for atrial fibrillation patients

- One-year clinical trial data for the next-generation, investigational, Sphere-360™ single-shot PFA catheter show impressive safety, performance, and efficiency results for paroxysmal Afib
- Dual-energy (RF/PF), focal Sphere-9™ catheter demonstrates efficacy for linear ablation in persistent AFib
- Medtronic continues legacy of leadership in innovation, showcasing arrhythmia management portfolio at Heart Rhythm Society annual meeting

GALWAY, Ireland and SAN DIEGO, April 26, 2025 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced positive clinical outcomes from two studies in atrial fibrillation (AFib) patients treated with the Affera™ family of technologies, including the next-generation Sphere-360™ single-shot pulsed field ablation (PFA) catheter and the groundbreaking Sphere-9™ combination mapping and dual-energy focal PFA catheter. Data were presented in High Impact Science Sessions at the Heart Rhythm Society 2025 Annual Meeting in San Diego; the Sphere-360 study was simultaneously published in the Heart Rhythm Journal.

Sphere-360 Study Safety and Performance

Sphere-360 is an investigational, first-of-its-kind, single-shot PFA mapping and ablation catheter for treatment of paroxysmal atrial fibrillation (PAF). Results for Sphere-360 at one year, in a prospective, single-arm, multi-center trial performed in European centers, demonstrated freedom from arrhythmia recurrence in 88% of patients, with chronically durable pulmonary vein isolation (PVI) in 98% of targeted veins and no reported safety events in a sub-group treated with the most optimized waveform. The Sphere-360 catheter has a large, conformable lattice design that can be modified into various shapes, is seamlessly integrated with the Affera Mapping and Ablation System and utilizes an 8.5 Fr sheath – the smallest in any single-shot PFA technology.

"The Affera technology is a sophisticated ecosystem, including an advanced, intuitive mapping system and catheters that are seamlessly integrated to offer treatment options for different cardiac arrhythmias. It is encouraging to see the promising results for Sphere-360, which can easily create circumferential lesions without the need for catheter rotation," said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. "The study results showed Sphere-360 has a promising safety and performance profile with zero serious adverse events observed. Upon approval, Sphere-360 will be a valuable addition to Medtronic's Affera system, which has been a game changer for Afib treatment and physician workflow."

Medtronic intends to begin its U.S. pivotal trial for the Sphere-360 catheter later this calendar year. Worldwide, Sphere-360 is currently investigational and not approved for sale or distribution.

Sphere-9 for Linear Ablation

Additionally, in a sub-analysis from the Sphere Per-AF IDE study, results demonstrated that the Sphere-9 catheter can be used safely and effectively to create linear lesions in persistent AF patients. Linear ablation is often used in conjunction with PVI to improve the chances of restoring a normal heart rhythm without recurrence in persistent AF patients. The Sphere Per-AF IDE study evaluated the safety, efficacy and efficiency of Affera and Sphere-9 in persistent AF and led to the FDA approval of Affera in October 2024.

"True to our Medtronic mission for patients and legacy of innovation, we are delivering our best-in-class technologies to physicians and improving care for AFib patients, and we are not slowing down," said Rebecca Seidel, president of the Cardiac Ablation Solutions business at Medtronic, which is part of the Cardiovascular portfolio. "These results signify another step

forward and energize us as we continue to earn and build our leadership position in electrophysiology every day."

Medtronic is the only company with two PFA offerings for physicians and patients. The PulseSelect™ Pulsed Field Ablation System offers physicians a safe, single-shot solution for pulmonary vein isolation (PVI) and is now available in more than 30 countries. The Affera system together with the Sphere-9 catheter enables physician treatment flexibility with its wide area focal design and 9mm lattice tip that can used with an 8.5Fr sheath. Affera is available in Europe, Australia and New Zealand, with global expansion ongoing.

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 paroxysmal 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 the Affera PFA system and the Sphere-9 catheter, visitMedtronic.com.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inGalway, 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 more than 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.

References

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