Medtronic News

Medtronic completes enrollment in pivotal trial evaluating first-of-its-kind pulsed field ablation catheter for patients with atrial fibrillation

SPHERE Per-AF will determine the safety and effectiveness of the Sphere-9 cardiac ablation and mapping catheter with the Affera mapping and navigation system

DUBLIN, Dec. 5, 2022 /PRNewswire/ -- Medtronic (NYSE:MDT) today announced the completion of enrollment and final treatment in the SPHERE Per-AF Trial, a U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) pivotal trial designed to evaluate the safety and effectiveness of the first-of-its kind Sphere-9™ pulsed field (PF) and radiofrequency (RF) ablation, and high density (HD) mapping catheter with the Affera cardiac mapping and navigation platform for the treatment of persistent atrial fibrillation (AF).

The investigational Medtronic technology includes the Affera mapping/navigation platform, designed to improve efficiencies by enabling intuitive HD mapping to diagnose arrhythmias and treat patients with one catheter. The Sphere-9 catheter combines mapping, navigation, and therapeutic capabilities and is the only catheter capable of delivering both RF and PF energies for ablation, providing physicians with the ability to customize treatment based on a patient's needs during an ablation procedure.

"During the trial, my observations and experience with the novel Affera system have been very promising," said Devi Nair, M.D., FHRS, Director of Cardiac Electrophysiology & Research, St. Bernards Medical Center, Jonesboro, Arkansas, a participating site in the SPHERE Per-AF trial. "Unlike conventional technologies, I've been impressed with the ability to both map and ablate with the option of dual energy sources, with one catheter. I look forward to the results of the trial and remain optimistically enthusiastic as I continue to understand the safety and efficacy of the Sphere 9 ablation catheter."

The SPHERE Per-AF Trial is a global, prospective, multicenter, randomized clinical trial. Since the trial's commencement in December 2021, the trial enrolled 477 patients with persistent AF across 23 centers in the U.S. and Europe. Patients will be assessed for 12 months for safety and efficacy.

"Treating the final patient in the fast-moving SPHERE Per-AF Trial builds on the exciting phase of innovation and growth at Medtronic over the last year, including the acquisition of Affera, our agreement to distribute a differentiated portfolio of left-heart access tools and devices to support a zero-exchange procedure workflow, and the continued progress in the development of PulseSelect, our organic PFA system," said Rebecca Seidel, president, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "Thanks to the innovation and expertise within Affera and the support of our Medtronic team, together we're able to continue to evaluate new, best-in-class solutions and commercialize a full, comprehensive portfolio to help physicians treat patients around the world."

Affera, Inc. was acquired by Medtronic in August 2022. The Affera product portfolio is not currently approved or available for sale or commercial use.

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 90,000+ 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 Twitter and 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.

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