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Medtronic announces FDA approval for early feasibility trial of Affera™ Mapping and Ablation System with Sphere-9™ Catheter for the treatment of ventricular tachycardia

The VT research will provide important clinical evidence in an underserved patient population

Medtronic plc, a global leader in healthcare technology, today announced approval from the United States Food and Drug Administration (FDA) to conduct an early feasibility study to evaluate the Affera™ Mapping and Ablation System with Sphere-9™ Catheter for treatment of sustained ventricular tachycardia (VT). VT is a potentially life-threatening abnormal heart rhythm affecting the lower chamber of the heart.

The Affera Mapping and Ablation System with Sphere-9 Catheter is an all-in-one, dual-energy pulsed field (PF) and radiofrequency (RF) ablation and high-density mapping catheter for use in cardiac electrophysiology ablation procedures.

“Physicians need better tools to treat VT safely and effectively, and early feasibility research is a positive step toward determining potential new options,” said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Services for the Mount Sinai Health System in New York City. “I am pleased to be involved in the study and look forward to getting started.”

The study will evaluate ablation treatment with Sphere-9 and the Affera system for patients who suffer from VT due to scarring from a prior myocardial infarction (heart attack). Primary endpoints include rate of device-or procedure-related serious adverse events (SAEs) following the ablation procedure and acute effectiveness at ablating the targeted VT. Patients enrolled at centers across the United States will be followed for six months post-ablation.

“We look forward to learning more about how the Sphere-9 Catheter, which offers physicians the ability to map and ablate with the option of choosing PF or RF, together with a large lattice-tip for managing the large target areas for ablation that typically present with VT, can be a useful tool for this challenging arrhythmia,” said Khaldoun Tarakji, M.D., MPH, vice president, chief medical officer, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. “Currently approved treatments for VT involve only RF energy and require physicians to use multiple mapping and ablation catheters with often long, inefficient

procedure times. PFA technology and the innovative Sphere-9 design could have a significant impact on patient care."

The early feasibility study will build on promising preclinical evidence in VT as well as extensive research demonstrating the efficacy and safety of Sphere-9 for treatment of persistent atrial fibrillation (Afib), another form of arrhythmia. Sphere-9 received CE Mark in 2023 for treatment of persistent Afib and is investigational in the U.S.

VT is a potentially life-threatening arrhythmia that causes the heart to beat abnormally fast.[1] Unlike AFib, VT affects the lower chamber of the heart and often presents after a heart attack or together with other advanced heart disease.[1,2] As a result, VT patients are treated with medications and often receive life-saving therapies from implanted defibrillators in the form of pacing or shocks.[1] Catheter ablation for VT is an established treatment option; however, outcomes have remained suboptimal[2] with little ablation tool innovation in recent years. As a result, a significant unmet need exists to improve patient care.[3]

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, 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, 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.

1. Sciria,C. et al. Trends and Outcomes of Catheter Ablation of Ventricular Tachycardia in Patients With Ischemic and Nonischemic Cardiomyopathy. Circ: Arr. and Elec. 2022; vol.15, no. 4.
2. 2019 HRS/EHRA/APHRS/LAHRS expert consensus statement on catheter ablation of ventricular arrhythmias.
3. Cheung, J, et al. Outcomes, Costs, and 30-Day Readmissions After Catheter Ablation of Myocardial Infarct–Associated Ventricular Tachycardia in the Real World: Nationwide Readmissions Database 2010 to 2015. Circ: Arr. and Elec.2018; vol. 11, issue 11.

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