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PulseSelect™ pulsed field ablation system receives approval in Japan, broadening global impact of paradigm-shifting AFib treatment

- Rapidly increasing adoption driven by new standard of safety, efficacy and efficiency with excellent physician feedback worldwide
- Only PFA system indicated for both paroxysmal and persistent AFib
- System designed to adapt to physician and any electrophysiology (EP) lab workflow

May 10, 2024 – Medtronic today announced regulatory approval of its PulseSelect™ pulsed field ablation (PFA) system in Japan, broadening the global reach of the proven safe and effective technology for treatment of paroxysmal and persistent atrial fibrillation (AFib) patients. The approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) was based on results from the pivotal PULSED AF trial, a global, multi-center IDE study, with centers in Japan, which evaluated the safety and effectiveness of PFA technology for AF ablation.

Since receiving CE Mark in Europe and the first-ever PFA approval by the U.S. Food and Drug Administration (FDA), cases have increased rapidly with more than 250 physicians globally successfully treating more than 3,000 patients with PulseSelect together with the company's bi-directional 10F FlexCath Contour™ sheath.

"We are seeing tremendous excitement and adoption of PulseSelect in every market we have launched, including the U.S., Europe and Canada. The positive feedback on safety profile, ease of handling, and its flexibility to be used with any mapping system has been consistent across many focal RF and single-shot shot users who have adopted it," said Rebecca Seidel, president of the Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "And now the expansion of PulseSelect into the important Japanese market is exciting for both physicians and for the patients they serve, who deserve the most advanced, safe, effective, and efficient care for AFib."

The PulseSelect PFA system was engineered with differentiated safety features and provides rapid, effective pulmonary vein isolation (PVI) through consistent and predictable energy delivery and catheter maneuverability. The system is designed to enable a seamless transition to PFA in a clinician's preferred workflow[1].

"The launch of the PulseSelect PFA catheter marks a new era in safety and an exciting shift in precision and efficiency in AFib treatment for my patients and those around the world," said Devi Nair, M.D., FHRS, Director of

Cardiac Electrophysiology & Research, St. Bernard's Medical Center & Arrhythmia Research Group, Jonesboro, Arkansas. "Designed for optimal safety and versatility, this catheter streamlines procedures with its intuitive workflow, empowering clinicians like me to deliver exceptional care efficiently."

Additionally, a new software upgrade is now available for PulseSelect, including an automated delivery mode which further simplifies the workflow and provides additional options for physicians to control pulsed field applications during the procedure. Upgrades have been completed across existing and new systems in Europe and Canada, are initiating in the U.S. and will expand to countries including Japan upon approval.

"During development, our team designed the system to enable future software enhancements in the field. We are happy to report the first software update that automates the delivery of pulsed field energy and enhances the efficiency of the procedure. This update has been successfully installed in Western Europe and Canada and we have received FDA approval in the U.S.," said Khaldoun Tarakji, M.D., MPH, vice president, chief medical officer, Cardiac Ablation Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "We will always be committed to innovation that meets physicians' needs in order to provide the best care for patients globally."

PulseSelect received CE Mark in November 2023 and was approved in the United States in December 2023.

About Atrial Fibrillation and Pulsed Field Ablation

AF is one of the most common and undertreated heart rhythm disorders, affecting more than 60 million people worldwide[2]. AF is a progressive disease, meaning it can become worse over time and can increase the risk of serious complications including heart failure, stroke and increased risk of death.[3-6] Prior to PFA, ablation technologies relied on thermal effects to target cardiac tissue and risk damage to additional collateral structures in the heart. PFA uses pulsed electric fields to efficiently isolate the pulmonary veins for the treatment of AF. Because the mechanism of cell death is non-thermal, the risk of collateral structure damage is potentially lower.

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.

1. Medtronic data on file. November 2023.
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Contacts:

Leslie Williamson	Ryan Weispfenning
Public Relations	Investor Relations
+1-612-227-5099	+1-763-505-4626

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