Medtronic News

New clinical data demonstrate excellent lesion durability with PulseSelect™ Pulsed Field Ablation System in real-world setting as approvals and adoption expand globally

- APHRS: New data confirm robust long-term durability and highly efficient procedure performed without fluoroscopy
- Successful launch in Japan follows recent reimbursement approval
- Approvals across APAC including China and Australia broaden reach for patients

GALWAY, Ireland and SYDNEY, Sept. 27, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced the presentation of clinical study results demonstrating a high rate of durable lesion formation for the PulseSelect™ Pulsed Field Ablation (PFA) System in treating atrial fibrillation (Afib). Invasive remapping conducted approximately two months post-ablation with the PulseSelect PFA System demonstrated durable isolation in 98% of pulmonary veins (PV) and 96% of patients had all veins isolated.

Results were presented as a late breaking clinical trial at the Asia Pacific Heart Rhythm Society (APHRS) meeting in Sydney, Australia.

"Real-world evidence on chronic lesion formation and durability is critical as use of PFA for the treatment of Afib rapidly increases, making these results impactful and timely for the electrophysiology community," said Devi Nair, M.D., FHRS, Director of Cardiac Electrophysiology & Research, St. Bernard's Medical Center & Arrhythmia Research Group, Jonesboro, Arkansas. "Our research shows that treatment with PulseSelect results in durable lesion formation, which is the cornerstone of successful pulmonary vein isolation and an important addition to previous evidence establishing the safety and effectiveness of this technology."

About the Study

A total of 25 AFib patients with persistent or paroxysmal AFib (56% paroxysmal, 52% male, 69±9 years) undergoing pulmonary vein isolation (PVI) with the PulseSelect PFA System were evaluated. Invasive remapping conducted in all patients (57±9 days post-ablation) demonstrated durable isolation in 98% of PVs (102/104), and 96% of patients (24/25) had all veins isolated.

All index ablation procedures were conducted using intracardiac echocardiography and electroanatomical mapping (EAM) without fluoroscopy. General anesthesia was used in 24 of 25 patients, and all patients were discharged on the same day. Average skin-to-skin procedure time was 36 minutes. Acute PV isolation was achieved in 100% of patients. There were no complications during an average follow-up of 74 days.

PulseSelect Global Expansion

Broad adoption of PulseSelect continues globally, with more than 10,000 cases performed worldwide. In the Asia Pacific (APAC) region, milestones include regulatory approvals in China and Australia and launch in Japan following reimbursement approval.

Prof. Hiroshi Tada, Professor of the Department of Cardiovascular Medicine, Faculty of Medical Sciences, University of Fukui, Japan, and President of the Japanese Heart Rhythm Society, said "PulseSelect is the first PFA catheter to receive reimbursement approval in Japan based on clinical trial results that include Japanese patients. We believe that the future widespread availability of this breakthrough technology under insurance coverage will be of great significance in the history of arrhythmia treatment in Japan."

"These important results clearly address the durability question and add to the real-world evidence for PulseSelect," said Rebecca Seidel, president, Cardiac Ablations Solutions business, which is part of the Cardiovascular Portfolio at Medtronic. "With expansion in new markets across the Asia Pacific region, physicians around the world are experiencing the benefits of

PulseSelect, including proven safety, efficacy, efficiency and now durability as well. We are thrilled to provide this important tool to physicians for the treatment of patients with AFib."

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 PulseSelect, visit Medtronic.com.

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 (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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