New Clinical Study Data Showcase Long-Term, Sustained Benefits Of Abbott's Volt™ PFA System For Patients With AFib

- Long-term data from the Volt CE Mark Study show strong results out to 12 months in patients receiving pulsed field ablation (PFA) therapy with the Volt™ PFA System
- The 12-month results of the Volt CE Mark Study confirm the long-term safety and efficacy of the Volt PFA System
- The data were presented at the 2025 Heart Rhythm Society (HRS) annual meeting

ABBOTT PARK, Ill., April 26, 2025 /PRNewswire/ -- Abbott (NYSE: ABT) has announced new data from its Volt CE Mark Study that show strong safety and efficacy out to 12 months for patients receiving pulsed field ablation (PFA) therapy with the Volt™ PFA System for the treatment of atrial fibrillation (AFib). The data also highlights the excellent safety profile of the Volt PFA System alongside the system's ability to achieve results with fewer therapy applications (*just 4.7 applications per vein on average*) than on-market competitive PFA systems.

PFA therapy works differently from traditional cardiac ablation approaches by delivering high energy electrical pulses to targeted areas of cardiac tissue causing abnormal heart rhythms. Abbott designed its Volt CE Mark Study to assess the impact of the Volt PFA System in two different patient groups – people battling paroxysmal atrial fibrillation (PAF) - *episodes that come and go* - as well as persistent AFib (PersAF) - *episodes that last longer than seven days*.

The 12-month data from the Volt CE Mark Study were presented at the 2025 Heart Rhythm Society (HRS) annual meeting held in San Diego (April 24-27, 2025) and simultaneously published in *Heart Rhythm*, the official journal of the Heart Rhythm Society.

Sustained Performance of the Volt PFA System
Data from the Volt CE Mark Study showed that after 12 months, Abbott's Volt PFA System delivered:

- **Outstanding long-term performance**. The Volt PFA System demonstrated sustained performance in both safety and effectiveness out to 12 months for patients with PAF and PersAF.
- **Freedom from arrhythmia**. 83.5% of PAF patients and 58.1% of PersAF patients remained free from atrial arrhythmia after 12 months – one of the lowest rates of reoccurrence in PAF patients in a long-term PFA study to date.
- **Quality of life (QoL) benefits**. After 12 months, the Volt CE Mark Study showed a significant QoL benefit for patients, with QoL assessment scores improving from 64.1 to 88.1.
- **Excellent safety profile**. After 12 months, just 2.7% of Volt patients had experienced a primary safety endpoint event with *zero patients* suffering from hemolysis (destruction of red blood cells), coronary artery spasm, pulmonary vein stenosis, acute kidney injury, or phrenic nerve injury – all potential challenges of PFA therapy.

"The long-term 12-month results from the Volt CE Mark Study paint a picture of a PFA system that performs exceptionally well in two different groups of patients – each with unique therapy needs and clinical approaches," said Prof. Gian-Battista Chierchia, director of the Atrial Fibrillation Program at the Heart Rhythm Management Institute at the University of Brussels in Belgium. "These long-term data provide us a strong picture of how the Volt PFA System will perform in clinical settings as we leverage PFA therapy for our patients."

To date, clinical experience following CE Mark has further confirmed that the Volt PFA System can support treating patients battling either PAF or PersAF, allowing the system to help as many patients as possible. The Volt PFA System also provides a single-catheter PFA approach, improves workflow and provides procedural flexibility by allowing for light sedation or general anesthesia. A new sub-analysis from the VOLT-AF IDE Study presented at HRS 2025 showed no significant difference in safety or acute effectiveness outcomes in cases performed under conscious or deep sedation when compared to procedures performed with general anesthesia.

"Our goal from the beginning with the Volt PFA System was to design a PFA system that would provide outstanding results in patients battling a range of atrial arrhythmias, and the latest data from the Volt CE Mark Study is confirmation that the system will truly impact patient care in a positive way," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business.

About the Volt CE Mark Study
Abbott's Volt CE Mark Study is a prospective, single-arm, non-randomized, multicenter study designed to demonstrate the safety and effectiveness of the Volt PFA System for the treatment of symptomatic, recurrent, drug-refractory PAF and PersAF. The study enrolled 150 patients at 11 sites across Europe and included a feasibility sub-study in which additional imaging assessments were collected to confirm the acute safety of the Volt PFA System.

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 114,000 colleagues serve people in more than 160 countries.

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