Abbott Receives CE Mark For Its Volt™ Pulsed Field Ablation System To Treat Patients With Abnormal Heart Rhythms

- Abbott's Volt™ PFA System is designed to provide a new therapy option for people battling heart rhythm disorders such as atrial fibrillation
- Pulsed field ablation – or PFA – uses high energy electrical pulses for ablation procedures that may offer benefits to targeting and treating tissue in the heart
- Abbott's Volt PFA System is designed to overcome limitations of existing PFA systems, providing improved workflows and a clearer indication of contact between the Volt PFA catheter and targeted tissue

ABBOTT PARK, Ill., March 27, 2025 /PRNewswire/ -- Abbott (NYSE: ABT) today announced it has received CE Mark in Europe for the Volt™ PFA System to treat patients battling atrial fibrillation (AFib). With the earlier-than-expected CE Mark, Abbott has begun commercial PFA cases in the EU with physicians who have already gained experience with the Volt PFA System within Abbott's PFA clinical studies. The company will further expand use of Volt in EU markets throughout the second half of the year.

Today, approximately 8 million Europeans over the age of 65 are living with AFib, a number expected to double over the next 30 years.[1,2] People living with AFib face an increased risk of stroke, heart failure and death, and many rely on cardiac ablation to treat the condition effectively. The Volt PFA System builds upon Abbott's leading electrophysiology (EP) portfolio by providing a single-catheter PFA approach, improving workflow by allowing for mapping, pacing, and ablating with a single catheter to safely and effectively treat patients with AFib.

CE Mark approval for the Volt PFA System was granted based on strong results from Abbott's Volt CE Mark study, a global clinical trial conducted at centers in Europe and Australia. The trial showed the Volt PFA System achieved pulmonary vein isolation (PVI) – the method of destroying tissue causing a patient's AFib – in 99.1% of veins during ablation procedures with far fewer energy applications than on-market competitive PFA systems.[3]

Following approval, initial cases were completed by Prof. Helmut Puererfellner at Ordensklinikum hospital in Linz, Austria; Prof. Roland Tilz at the University Heart Center in Luebeck, Germany; Prof. Gian-Battista Chierchia at the University of Brussels in Belgium; and Prof. Peter Loh at the University Medical Center Utrecht in the Netherlands.

"The launch of Abbott's Volt PFA system marks a major milestone in the evolution of electrophysiology across Europe and signals we're moving beyond early therapy approaches to new systems that incorporate key physician feedback and clinical insights to optimize PFA therapy," said Prof. Puererfellner. "PFA is significantly changing our approach to treating patients and it's exciting to see the Volt PFA System build on the therapy's potential and bring new benefits to clinical teams so we can improve the lives of more patients battling conditions like AFib."

Volt™ PFA System: Driving New Advancement in the PFA Market
PFA works differently from traditional ablation approaches by delivering high energy electrical pulses to targeted areas of cardiac tissue causing abnormal heart rhythms. As a result, PFA can reduce the risk of damaging adjacent tissue in patients with complex disease or anatomy.

Yet current on-market competitive PFA systems have required several therapy applications with a catheter positioned in various locations due to a lack of visualization or contact assessment. By integrating with Abbott's EnSite™ X EP system, the Volt PFA System is designed to address such limitations and provide:

- **Simplified workflow**. The single-catheter integrated approach of the Volt PFA system improves clinical workflow and provides real-time contact visualization to help physicians position the catheter for therapy delivery.
- **Efficient energy delivery**. The proprietary balloon-in-basket design of the Volt™ PFA Catheter, Sensor Enabled™, allows for efficient energy transfer directly to the targeted tissue to stop the heart's erratic signals, minimizing the number of therapy applications needed.
- **Procedural flexibility**. Patients undergoing a minimally invasive ablation procedure with the Volt PFA Catheter, Sensor Enabled, can be placed under light sedation or general anesthesia based on physician and hospital preference.

In addition, the Volt PFA catheter's integration with EnSite X system allows for clearer visualization and navigation for accurate positioning of the Volt PFA catheter to treat tissue. The One System Solution provided by EnSite X can accommodate all EP procedures and compatible technologies.

"While PFA is a relatively new therapy option, we've incorporated lessons learned from first-generation devices and designed the Volt system to simplify PFA procedures while making them more efficient," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business. "Clinical data has also shown that the Volt catheter's cutting-edge design helps physicians achieve pulmonary vein isolation in fewer ablation attempts and less therapy applications for improved patient outcomes."

Clinical and Regulatory Progress Across Abbott's PFA Portfolio
Abbott's Volt PFA System is currently under evaluation in the VOLT-AF Investigational Device Exemption (IDE) Study. The study completed enrollment last year – four months ahead of the anticipated timeline. Nearly 400 patients are enrolled in the trial, and Abbott anticipates completing the 12-month follow-up for the study later this year.

In addition, the company has also made significant progress in clinical studies evaluating Abbott's focal PFA technology, which is designed to provide focused energy delivery for the creation of targeted lesions at specific points in the heart. Enrollment was recently completed ahead of schedule in Abbott's FOCALFLEX CE trial assessing the performance of the TactiFlex™ Duo Ablation Catheter, Sensor Enabled™. Enrollment is also underway in the FlexPulse IDE trial evaluating TactiFlex Duo in the U.S.

Abbott has also recently received regulatory approval in the U.S. and Europe for a 13F sizing of the company's Agilis™ NxT Steerable Introducer, Dual Reach™, which makes the Agilis system compatible with larger catheters, including those used for PFA therapy.

For U.S. important safety information go to:
Agilis™ NxT Steerable Introducer, Dual Reach™
https://abbo.tt/Agilis_ISI

EnSite™ X EP System
https://www.cardiovascular.abbott/us/en/hcp/products/electrophysiology/mapping-systems/ensite-x.html

About Abbott
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Connect with us at www.abbott.com and on LinkedIn, Facebook, Instagram, X and Youtube.

[1] *Fact Sheets for Press*. European Society of Cardiology. (n.d.-a). https://www.escardio.org/The-ESC/Press-Office/Factsheets

[2] *Atrial fibrillation set to affect more than 14 million over-65s in the EU by 2060* European Society of Cardiology. (n.d.). https://www.escardio.org/The-ESC/Press-Office/Press-releases/Atrial-fibrillation-set-to-affect-more-than-14-million-over-65s-in-the-EU-by-2060

[3] Tilz, R.R. (2025, January 17) Acute results demonstrate safety and effectiveness of balloon-based pulsed field ablation system for de novo PVI in PAF and PersAF [Late Breaking Presentation]. AF Symposium 2025, Boston MA, USA.

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For further information: Abbott Media: Cole Heath (651) 421-3655 OR Abbott Financial: Michael Comilla (224) 668-1872

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