Late-Breaking Data Presentations Showcase The Safety And Efficacy Of Abbott's Ablation Catheters To Treat People With Atrial Fibrillation

- Positive 12-month results from the VOLT-AF IDE Study presented at the AF Symposium and simultaneously published in *JACC: Clinical Electrophysiology*, reinforce the Volt™ Pulsed Field Ablation (PFA) System's industry-leading success rate for treating AFib[1]
- New data from the FOCALFLEX CE Mark trial demonstrate the safety and efficacy of the TactiFlex™ Duo Ablation Catheter, Sensor Enabled™, to significantly reduce AFib episodes for complex cases[2]

ABBOTT PARK, Ill., Feb. 6, 2026 /PRNewswire/ -- Abbott (NYSE: ABT) today announced new clinical data from two late-breaking presentations at AF Symposium in Boston (February 5-7, 2026) that demonstrate the strong safety and efficacy of the company's minimally invasive therapies to treat people with atrial fibrillation (AFib). The results include 12-month findings that reinforce the long-term safety and performance of Abbott's Volt™ Pulsed Field Ablation (PFA) System, which were simultaneously published in *JACC: Clinical Electrophysiology*. Positive results were also presented on Abbott's TactiFlex™ Duo Ablation Catheter, Sensor Enabled™, a dual-energy, focal ablation catheter engineered to allow physicians to tailor how they deliver AFib therapy.

Sustained performance of the Volt PFA System
Twelve-month data from the VOLT-AF Global IDE study found that the Volt PFA System had an industry-leading success rate (84.2%) of freedom from documented rhythm recurrence among all competitive PFA products to treat AFib episodes that come and go (Paroxysmal AFib or PAF).[1]

Volt also delivered strong results as a treatment option for AFib episodes that last longer than seven days (Persistent AFib or PersAF), with nearly 68% of patients remaining free from an additional episode following a Volt ablation.[1]

Additional key findings of the single-arm trial conducted at approximately 40 centers in the United States, Europe, Canada and Australia through one year include:[1]

- Physicians were able to use fewer therapy applications (*just 4.6 applications per vein on average)* than other on-market competitive PFA systems.
- The trial found less than 6% of patients required a repeat ablation, one of the lowest rates in the industry.
- Patients reported a significant improvement in quality-of-life (QoL) as measured by the Atrial Fibrillation Effect on QualiTy-of-life (AFEQT) score. This self-assessment – which evaluates changes to a person's overall symptoms and social well-being – show scores rose from 63.6 to 91.4 for PAF patients treated with Volt and from 64.2 to 91.4 for PersAF patients. The study also found zero patient complications related to either an unintended injury to the esophagus, or the breakdown of red blood cells (hemolysis), which can cause sudden kidney damage.

"The data for Volt confirms what I see firsthand in the procedure room with this next-generation PFA device," said Atul Verma, M.D., director of the Division of Cardiology at McGill University Health Centre and McGill University in Montreal, Canada, who treated patients as part of the VOLT-AF IDE study and presented the late-breaking data at AF Symposium. "The system's unique design enables a high degree of freedom from AFib for patients, and its impressive safety profile reduces PFA-specific complications such as hemolysis, which negatively impacts other parts of the body."

The Volt PFA System secured U.S. Food and Drug Administration (FDA) approval and CE Mark in Europe last year. Commercial cases have begun in the U.S. and expansion in Europe continues.

Strong data supports TactiFlex Duo Ablation Catheter, Sensor Enabled
Six-month data presented from the FOCALFLEX Global CE Mark trial confirmed the safety and effectiveness of TactiFlex Duo for treating more complex cases of AFib. The trial found a clinically meaningful success rate (81%) of freedom from documented rhythm recurrence among PAF patients. [2]

Patient self-reported quality-of-life scores also climbed from 64.4 to 86.4.[2] This data from more than 20 centers in the European Union, United Kingdom and Australia contributed to the device's recent CE Mark approval.

TactiFlex Duo is designed for focal ablation, using a dual-energy platform, which gives physicians the ability to tailor AFib therapy delivery in two ways instead of a single energy mode. Experts use the catheter to target and treat an irregular heart rhythm with either extreme heat (radiofrequency) or high-energy electrical pulses (PFA) based on a patient's individual needs and anatomy, including the most challenging cases.

In addition to the CE Mark study, Abbott also completed enrollment last year for the FLEXPULSE Global IDE trial to evaluate TactiFlex Duo as an AFib therapy. Last October, the FDA granted Breakthrough Device Designation for TactiFlex Duo to treat Ventricular Tachycardia – a potentially life-threatening fast heart rate requiring immediate medical attention – using PFA.

"With the rising rates of AFib around the world, data from the Volt PFA and TactiFlex Duo trials help empower physicians with further confidence in using these devices to treat people with AFib – from the recently diagnosed to the most complex cases," said Christopher Piorkowski, M.D., chief medical officer of Abbott's electrophysiology business. "These studies help solidify our treatment offerings for AFib as we strive to challenge the status quo to develop even better tools that physicians can rely on to

care for their patients."

In addition, a late-breaking data presentation on Abbott's Amulet device will be presented on Friday, Feb. 6 between 5:30 – 7 p.m. Eastern from the VERITAS Amulet 360 Pivotal Study.

For U.S. important safety information go to:
Volt™ PFA System
https://www.cardiovascular.abbott/us/en/ep-clinical-evidence/volt-clinical-evidence.html

TactiFlex™ Duo Ablation Catheter, Sensor Enabled™ is approved for investigational use only in the U.S.

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Connect with us at www.abbott.com and on LinkedIn, Facebook, Instagram, X and YouTube.

[1] Verma, A. (2026, February 5) 12-Month Safety and Effectiveness of a balloon-in-basket PFA system for de novo PVI to treat PAF and PsAF: Results from the VOLT-AF IDE Study [Late Breaking Presentation]. AF Symposium 2026, Boston MA, USA.

[2] Deisenhofer, I. (2026, February 5) Safety and Effectiveness of the TactiFlex Duo System: 6-Month Results of the FOCALFLEX Study [Late Breaking Presentation]. AF Symposium 2026, Boston MA, USA.

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