Abbott Showcases Strength Of Its Technologies To Address Abnormal Heart Rhythms With Late-Breaking Clinical Data At Heart Rhythm Society 2026

- Four late-breaking presentations at Heart Rhythm Society 2026 in Chicago highlight strong clinical evidence across Abbott's growing pulsed field ablation and novel cardiac pacing portfolios
- Six-month results from the FlexPulse IDE study for the TactiFlex™ Duo Ablation Catheter, Sensor Enabled™, reveal positive outcomes for treating complex AFib cases
- New data from the Volt CE Mark Extension Cohort trial for the Volt™ PFA System, demonstrate the strong safety, efficacy and efficiency of treatment of AFib cases for posterior wall ablation
- Two new conduction system pacing studies showcase initial results of Abbott's investigational UltiSynq™ CSP implantable cardioverter-defibrillator lead and a first-in-human evaluation of the investigational AVEIR™ CSP leadless pacemaker system

ABBOTT PARK, Ill., April 25, 2026 /PRNewswire/ -- Abbott (NYSE: ABT) today announced new late-breaking data from four trials that demonstrate strong clinical outcomes within its pulsed field ablation (PFA) and conduction system pacing (CSP) portfolios to treat heart rhythm disorders.

The data include six-month results from the FlexPulse IDE study, which examines treating complex atrial fibrillation (AFib) cases with the TactiFlex™ Duo Ablation Catheter, Sensor Enabled™, as well as new clinical evidence for posterior wall ablation with the Volt™ PFA System. Data were also presented for Abbott's ASCEND CSP IDE trial for the company's investigational UltiSynq™ CSP implantable cardioverter-defibrillator (ICD) lead, as well as a first-in-human evaluation of the LEAP2 chronic early feasibility trial for the investigational AVEIR™ CSP leadless pacemaker system.

Positive results support TactiFlex Duo Ablation Catheter, Sensor Enabled
New six-month data from the FlexPulse IDE study provide early insights showing positive patient outcomes with Abbott's TactiFlex Duo Ablation Catheter, Sensor Enabled, and confirms the strong safety and efficacy profile seen in the CE Mark study for treating complex AFib cases. The catheter provides physicians with two energy modes to tailor therapy based on a patient's complex disease or anatomy: radiofrequency – which uses heat energy that destroys tissue responsible for erratic heart signals – and PFA, which uses high energy electrical pulses that destroy the cells causing abnormal heart rhythms.

The late-breaking six-month data for the 188-patient FlexPulse IDE study show[i]:

- The majority (87%) of patients reported being free from documented arrhythmias.
- A high safety profile (98.3%) with no major safety events.
- The majority (93.3%) of patients were treated exclusively with PFA, demonstrating that this energy source alone was successful in treating complex cases.
- Physicians efficiently treated their patients – 93.9% did not require an additional ablation after the first round of therapy.

"The Abbott TactiFlex Duo catheter offers the convenience of seamlessly switching treatment between radiofrequency and pulsed field ablation based upon the patient's anatomy and their personalized ablation plan," said Jonathan P. Piccini, M.D., professor of medicine, Duke University Medical Center, who presented the late-breaking data at HRS. "While RF has long been a well-established ablation approach, with this study, we have been able to show that the TactiFlex Duo's point-to-point PFA is an effective approach for a significant number of our patients."

The FlexPulse IDE study was designed to secure U.S. Food and Drug Administration (FDA) approval for the TactiFlex Duo. The catheter received CE Mark in Europe earlier this year.

Promising first outcomes for Abbott's investigational conduction system pacing devices
Results from two late-breaking clinical trials evaluated Abbott's investigational leadless and traditional pacing/defibrillation CSP technologies designed to deliver left bundle branch pacing (LBBP), an approach intended to more closely replicate the heart's natural electrical activation. Both data presentations were simultaneously published in *Heart Rhythm*.

The ASCEND CSP IDE trial evaluated the investigational high-voltage UltiSynq CSP ICD lead designed to be implanted in the left bundle branch (LBB) area or the right ventricle to deliver both pacing and defibrillation. The three-month data show UltiSynq CSP successfully met the study's pre-specified primary safety and effectiveness endpoints. Key findings included:[ii]

- A high safety profile (97.5%) with no lead-related major safety events reported.
- A high success rate (99%) meeting left bundle branch area pacing (LBBAP) criteria which can be compared to results from previously reported trial(s). An 86% success rate was met using the more stringent LBBP or likely LBBP criteria. An average of fewer than one (0.9) repositioning attempt per patient was also achieved.
- 100% defibrillation success, with the majority (92.5%) achieving first shock success at 20J. No patients required repositioning of the ICD lead to achieve effective defibrillation.
- Stable electrical performance at three months, with no inappropriate therapies delivered due to P-wave or T-wave oversensing.

"Physicians are increasingly using left bundle area pacing for pacemaker patients, because it is associated with improved physiological activation compared with traditional pacing on the right side of the heart," said Rahul N. Doshi, M.D., FHRS,

FACC, professor of medicine at Arizona State University. "The data from the ASCEND trial show that an ICD lead designed for physiologic pacing can support restoration of normal heart rhythms when placed in the left bundle branch area. These early results suggest the potential to extend the benefits of physiologic pacing to ICD patients in an efficient manner."

Abbott also presented late-breaking results from a first-in-human clinical study evaluating Abbott's investigational AVEIR™ CSP leadless pacemaker system. The one-month data from the 19-patient study found a high implantation success rate along with:[iii]

- Delivery of pacing that closely followed the heart's natural electrical pathways.
- Reliable electrical performance and functioning at the time of implant and through the first month of follow-up.
- Consistent communication between devices in a dual-chamber pacemaker setting.

New Volt PFA System data confirms freedom from AFib recurrence
Late-breaking six-month data from the Volt CE Mark Extension Cohort trial demonstrated positive outcomes for patients in which the posterior wall of the heart was treated in addition to the standard treatment.

New data from the Volt CE Mark Extension Cohort trial show:[iv]

- Physicians cited the device's ease of use and intuitive design as contributors to efficiently treat their patients with fewer therapy applications (4.1 applications per vein and 10.7 per PWI on average) compared to other on-market PFA systems.
- A high safety profile with no reported patient or procedure-related complications.

The Volt PFA System secured FDA approval and CE Mark in Europe last year.

"Treating abnormal heart rhythms is not a siloed or one-size-fits-all approach, which is why Abbott is creating a holistic cardiovascular portfolio that empowers physicians to care for a wide range of arrhythmias," said Priya Jagasia, divisional vice president of regulatory, clinical, reimbursement and strategic initiatives at Abbott. "The data from these clinical trials serve as a cornerstone for the new innovations we're developing to help people live healthier lives."

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™, AVEIR™ CSP Leadless Pacemaker System, and UltiSynq™ CSP are approved for investigational use only in the U.S.

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 122,000 colleagues serve people in more than 160 countries.

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

---

[i] Piccini, J. (2026, April 25). *Safety and Effectiveness of a Dual-Energy Focal Ablation Catheter to Treat Paroxysmal Atrial Fibrillation: 6-Month Results of the FlexPulse IDE Study* [Late Breaking Podium]. Heart Rhythm, Chicago, IL, US.

[ii] Schaller, R. (2026, April 25) Safety and efficacy of a novel ICD lead for LBBAP: Results from the ASCEND CSP trial [Late Breaking Presentation]. Heart Rhythm Society 2026, Chicago IL, USA.

[iii] Reddy, V. (2026, April 25) LEAP2: A first-in-human study of a chronically-implanted novel leadless pacemaker for conduction system pacing [Late Breaking Presentation]. Heart Rhythm Society 2026, Chicago IL, USA.

[iv] Sanders, P. (2026, April 24). *6-Month Safety and Effectiveness of Balloon-Based PFA System Left Atrial Posterior Wall Ablation: Results from the Volt CE Mark Extension Cohort* [Late Breaking Poster]. Heart Rhythm, Chicago, IL, US.

SOURCE Abbott

For further information: Abbott Media: Shelley Lange, (612) 346-3514; Abbott Financial: Michael Comilla, (224) 668-1872

Additional assets available online: Photos