Abbott Advances Pulsed Field Ablation Clinical Studies And Launches New Technology To Support Advanced Cardiac Mapping

- Enrollment completed ahead of schedule in the global IDE for Abbott's Volt™ PFA System
- Global FOCALFLEX trial now underway for Abbott's TactiFlex™ Duo Ablation Catheter, Sensor Enabled™
- Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™, receives U.S. Food and Drug Administration clearance, begins commercial launch

ABBOTT PARK, Ill., Oct. 10, 2024 /PRNewswire/ -- Abbott (NYSE: ABT) announced today it has achieved new major milestones to support the company's growing suite of pulsed field ablation (PFA) solutions in electrophysiology: early completion of enrollment in the VOLT-AF IDE Study supporting the Volt™ PFA System, and the launch of the FOCALFLEX trial to assess the company's TactiFlex™ Duo Ablation Catheter, Sensor Enabled™ (SE), which will be used in the treatment of patients with paroxysmal atrial fibrillation. Together, these two studies represent significant advances for the future of two Abbott PFA catheters, which are being developed as important tools for physicians treating people with abnormal heart rhythms like atrial fibrillation (AFib).

In addition, Abbott also announced U.S. Food and Drug Administration (FDA) clearance of the company's Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™, which will further support mapping of both PFA and radiofrequency (RF) ablation cases, where visualization of cardiac anatomy is critical to ensure the best outcomes for people undergoing ablation procedures.

"It was exciting to participate in the VOLT-AF IDE Study to help assess a next-generation PFA catheter that incorporates new design concepts we believe will advance PFA technology and improve patient outcomes," said Monica Lo, M.D., an electrophysiologist with Arkansas Heart Hospital who specializes in complex arrhythmias. "Only through studies like VOLT-AF and Abbott's new FOCALFLEX trial, can we fully understand and safely deploy the next generation of AFib treatments to help people enjoy life free from complex heart rhythm conditions."

New Advancement in Pulsed Field Ablation, Treating AFib
Historically, patients requiring a cardiac ablation procedure to treat conditions likeAFib received RF ablation, which uses heat to destroy tissue responsible for erratic heart signals, or cryogenic ablation, which freezes tissue. Instead of heat or extreme cold, PFA uses high energy electrical pulses to destroy the cells causing abnormal heart rhythms, which can reduce the risk of damaging adjacent tissue in patients with complex disease or anatomy.

PFA represents a promising opportunity to treat people with abnormal heart rhythms with new technology that may offer safety advantages* that can reduce known risks of traditional ablation therapies. However, existing early-generation PFA systems have limitations, including the lack of three-dimensional visualization and coupling with a 3D cardiac mapping system*. Other limitations that Abbott's PFA systems were designed to address include no indication of catheter-tissue contact and repeat ablations to ensure favorable patient outcomes*. Increased interest in Abbott's PFA system propelled enrollment in the U.S. VOLT-AF IDE Study to be completed four months ahead of the anticipated timeline, enrolling almost 400 patients in just three months.

Abbott's investigational Volt PFA System was designed to overcome prior limitations in PFA systems by pairing a balloon-in-basket catheter with Abbott's EnSite™ X EP System, an industry-leading heart mapping solution. The unique basket shape of the catheter's energy delivery area paired with the balloon are designed to effectively transfer Abbott's optimized waveform energy to the tissue by ensuring better catheter contact and stability during the procedure*. Another unique feature of Abbott's PFA catheter is how the platform's PFA generator and the EnSite X EP System are designed to give physicians the ability to specifically target lesions and ablate the exact area(s) of the heart that are triggering arrhythmia.

In addition to the VOLT-AF IDE Study, Abbott's global FOCALFLEX Pulsed Field Ablation Study is also now underway to assess the company's TactiFlex Duo Ablation Catheter, Sensor Enabled. This catheter is designed as a dual-energy ablation solution offering both PFA and RF energy delivery, and will also be assessed in the FLEXPULSE IDE, which is expected to launch in the U.S. soon, with about 200 patients at 25 sites.

Where the Volt PFA System is designed as a "single shot" PFA approach, the TactiFlex Duo Ablation Catheter, SE is a "focal" or "point-by-point" approach that aims to deliver the safety and efficiency of PFA with more flexible and focused energy. Designed on Abbott's TactiFlex Ablation Catheter, Sensor Enabled, known for its stability during procedures due to its novel flexible tip, the TactiFlex Duo Ablation Catheter, SE aims to offer physicians another option for delivering PFA and/or RF to patients with greater versatility to precisely target specific areas of tissue within the heart.

"There's immense value in exploring different therapy options for patients to treat abnormal heart rhythms because each case is unique," said professor Prash Sanders, M.B.B.S., Ph.D., director of the Centre for Heart Rhythm Disorders at the University of Adelaide in Australia, who conducted the first procedures with the TactiFlex Duo Ablation Catheter, Sensor Enabled for the FOCALFLEX trial. "Abbott improved upon limitations of first-generation systems and has successfully advanced its approach to PFA beyond those initial systems that have come to market."

Abbott's Advanced Cardiac Mapping Solutions Support Improved Outcomes
As ablation innovations evolve, a key element of effective treatment continues to be the use of heart mapping. Accurate mapping for RF procedures has been critical in electrophysiology, and the adoption of mapping for PFA procedures continues to grow. Abbott has seen increased reliance on its mapping technology as more physicians begin to explore the use of PFA for patients.

With its recent FDA clearance, the Abbott Advisor HD Grid X Mapping Catheter, Sensor Enabled, offers a first-of-its-kind electrode configuration for high-density heart mapping. This design is intended to make physicians more aware of electrical signals of the heart, regardless of catheter placement during an ablation procedure.

For U.S. important safety information go to:
TactiFlex™ Ablation Catheter, Sensor Enabled™
https://www.cardiovascular.abbott/us/en/hcp/products/electrophysiology/ablation-technology/tactiflex-se-ablation-catheter/indications-safety-warnings.html

Advisor™ HD Grid Mapping Catheter, Sensor Enabled™
https://www.cardiovascular.abbott/us/en/hcp/products/electrophysiology/diagnostic-catheters/advisor-hd-grid/about.html

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

Investigational/Under-Development Products
*Devices or products referenced are INVESTIGATIONAL and/or UNDER DEVELOPMENT. Product specifications or proposed intended uses are design goals and subject to change.

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