Boston Scientific

Second phase of ADVANTAGE AF study of FARAPULSE™ Pulsed Field Ablation System meets primary safety and efficacy endpoints

Trial achieves positive results in the treatment of persistent atrial fibrillation

MARLBOROUGH, Mass. and SAN DIEGO, April 24, 2025 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive 12-month primary endpoint results from the second phase of the ADVANTAGE AF clinical trial evaluating the use of the FARAPULSE™ Pulsed Field Ablation (PFA) System* and adjunctive use of the FARAPOINT™ PFA Catheter in patients with persistent atrial fibrillation (AF). Key findings from the study were presented at the second annual PFA Live Case Summit in San Diego and simultaneously published in *Circulation*.

Persistent AF, which accounts for approximately 25%[1] of all AF cases, is an abnormal, rapid heartbeat that lasts for at least seven days in a row and can lead to complications such as blood clots, stroke and heart failure. The second phase of the ADVANTAGE AF trial studied the FARAWAVE™ PFA Catheter for both pulmonary vein isolation (PVI) and posterior wall ablation (PWA) and the FARAPOINT PFA Catheter for cavotricuspid isthmus (CTI) ablation to treat typical atrial flutter (AFL), a type of heart rhythm disorder. All patients in the trial were continuously monitored after their procedure with the LUX-Dx™ Insertable Cardiac Monitor (ICM) System, which is designed to detect recurrence of cardiac arrhythmias and assess AF burden. Findings from the trial met all pre-specified safety and effectiveness endpoints and demonstrated:

- 73.4% freedom from AF, AFL and atrial tachycardia (AT), which exceeded the performance goal of 40% or higher.
- A safety event rate of 2.4% and no reports of pulmonary vein stenosis, atrio-esophageal fistula or phrenic nerve palsy which met the performance goal of 12% or lower.
- 81.0% freedom from symptomatic documented AF recurrence, which is defined as arrhythmia, clinical intervention or use of escalated or new Class I/III anti-arrhythmic drugs.
- 71.6% of patients had virtually no atrial arrhythmia (AA) burden, in which data shows lower AA burden can be associated with fewer clinical interventions and improvements in quality of life and 52% of patients had no residual AA events after the blanking period.
- 96.4% of patients treated with the FARAPOINT PFA Catheter had no recurrence of AFL.

"Continuous rhythm monitoring in phase two of the ADVANTAGE AF study allowed for a detailed picture of patients' cardiac rhythm after ablation, including asymptomatic AF recurrence, which is not often captured in U.S. Food and Drug Administration clinical trial monitoring but is important for the ability to provide more individualized care to patients," said Vivek Reddy, M.D.**, director, Cardiac Arrhythmia Services, Mount Sinai Health System and Leona M. and Harry B. Helmsley Charitable Trust professor of medicine, Cardiac Electrophysiology, Icahn School of Medicine and study principal investigator. "The data collected in this trial continues to support the FARAPULSE PFA System as a safe and effective therapy, now with evidence highlighting positive results for its use in treating patients who suffer from persistent AF."

This prospective, single arm trial included 255 patients enrolled at 29 U.S. sites who were treated with the FARAWAVE PFA Catheter, and of those, 141 patients also received CTI ablation with the FARAPOINT PFA Catheter for AFL. The FARAPOINT PFA Catheter is a navigation-enabled point catheter that uses a smaller ablation footprint to create focal and linear-shaped lesions and integrates with the Boston Scientific OPAL HDx™ Mapping System to provide visualization of catheter placement during procedures.

"These positive study results are an important step forward in the continued innovation of the proven FARAPULSE PFA System and our broader portfolio of products that treat AF," said Brad Sutton, M.D., chief medical officer, AF Solutions, Boston Scientific. "The performance of the devices in this trial – the FARAPOINT and FARAWAVE PFA Catheters as well as the LUX-Dx ICM System – is an encouraging sign as we work towards expanding our portfolio to provide physicians with an even more robust toolset to treat the growing number of patients with AF."

Boston Scientific anticipates U.S. Food and Drug Administration approval to expand the instructions for use labeling for the FARAPULSE PFA System to include persistent AF as well as European and U.S. regulatory approvals for the FARAPOINT PFA Catheter in the second half of 2025.

Learn more about the ADVANTAGE AF study here.

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As a global medical technology leader for more than 45 years, we advance science for life by providing a broad range of high-performance solutions that address unmet patient needs and reduce the cost of health care. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at **www.bostonscientific.com** and connect on **LinkedIn** and **X**, formerly Twitter.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans and product performance and impact, clinical trials, and new and anticipated product approvals and launches. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: economic conditions, including the impact of foreign currency fluctuations; future U.S. and global political, competitive, reimbursement and regulatory conditions, including changing trade and tariff policies; geopolitical events; manufacturing, distribution and supply chain disruptions and cost increases; disruptions caused by cybersecurity events; disruptions caused by public health emergencies or extreme weather or other climate change-related events; labor shortages and increases in labor costs; variations in outcomes of ongoing and future clinical trials and market studies; new product introductions; expected procedural volumes; the closing and integration of acquisitions; demographic trends; intellectual property; litigation; financial market conditions; the execution and effect of our business strategy, including our cost-savings and growth initiatives; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this document.

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*CAUTION: Investigational Device. Limited by Federal (or US) law to investigational use only. Ablation of patients with persistent atrial fibrillation or ablation beyond pulmonary vein isolation are outside the labeled indication(s) for use of the FARAWAVE™ PFA Catheter with the FARAPULSE PFA System. The FARAWAVE™ NAV PFA Catheter was not used in this study. The second phase of the trial included the addition of studying the focal FARAPOINT™ Pulsed Field Ablation Catheter for cavotricuspid isthmus (CTI) ablation to treat typical atrial flutter, which is not available for sale.

***Dr. Vivek Reddy is a paid consultant of Boston Scientific Corporation. He has not been compensated in connection with this press release.*

[1]Zoni-Berisso M, Lercari F, Carazza T, Domenicucci S. Epidemiology of atrial fibrillation: European perspective. *Clin Epidemiol.* 2014;6:213-220. doi: 10.2147/CLEP.S47385

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Additional assets available online: Photos (1)

https://news.bostonscientific.com/2025-04-24-Second-phase-of-ADVANTAGE-AF-study-of-FARAPULSE-TM-Pulsed-Field-Ablation-System-meets-primary-safety-and-efficacy-endpoints