Late-breaking data presented at AF Symposium 2025 highlight key Boston Scientific therapies for management of patients with atrial fibrillation

First phase of ADVANTAGE AF clinical trial achieves safety and effectiveness endpoints for treatment of drug-resistant, symptomatic, persistent atrial fibrillation with the FARAPULSE™ Pulsed Field Ablation System

Sub-analysis from OPTION clinical trial highlights consistent safety and efficacy outcomes with the WATCHMAN FLX™ Left Atrial Appendage Closure Device post cardiac ablation in both concomitant and sequential procedures

MARLBOROUGH, Mass., Jan. 16, 2025 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced data supporting the use of the FARAPULSE™ Pulsed Field Ablation (PFA) System* and the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device, respectively, during a late-breaking science session at AF Symposium 2025.

ADVANTAGE AF clinical study

Currently, the FARAPULSE PFA System is approved for pulmonary vein isolation (PVI) in patients who have paroxysmal AF, an irregular heartbeat that occurs occasionally and typically spontaneously resolves back to normal rhythm. The ADVANTAGE AF study examined use of the FARAPULSE PFA System for both PVI and posterior wall ablation (PWA) in patients who have persistent AF, where individuals experience an irregular or rapid heartbeat that lasts longer than seven days and which represent 25% of all AF cases.[1] The prospective, single arm trial included 260 patients enrolled at 43 global sites who were drug intolerant to at least one Class I/III anti-arrhythmic drug (AAD).

Key findings from the study through 12 months included:

- The primary safety endpoint – defined as serious adverse events related to either the use of an ablation catheter or the ablation procedure within seven days of the primary procedure and pulmonary vein stenosis or atrio-esophageal fistula out to 12 months – was met with a 2.3% event rate.
- The primary effectiveness endpoint – defined as freedom from AF, atrial flutter, atrial tachycardia, re-ablation, cardioversion and use of a new or escalated dose of Class I/III AAD or amiodarone – was met at 63.5%.
- The symptomatic AF recurrence-free rate was 85.3% and observationally, among physicians that performed three or more procedures, the symptomatic recurrence-free rate increased to 91.8%.
- There were no reported incidences of stroke, pulmonary vein stenosis, atrio-esophageal fistula or major access complications.

"In addition to the positive safety and efficacy outcomes achieved in the ADVANTAGE AF study, a significant number of patients were able to discontinue AADs as well as see greater improvements in quality of daily life," said Vivek Reddy, M.D.**, director of electrophysiology, Mount Sinai Fuster Heart Hospital, New York and study principal investigator. "As the population of patients living with AF continues to grow, data from trials such as ADVANTAGE AF further support the paradigm shift to PFA as a treatment for patients who are living with persistent and other complex forms of AF."

OPTION trial sub-analysis

The late-breaking session also included a prespecified sub-analysis from the OPTION clinical trial that built upon the positive primary endpoint results presented at the American Heart Association 2024 meeting and published in *The New England Journal of Medicine*.[2] In line with the overall 36-month outcomes from this first head-to-head study of the WATCHMAN FLX device and direct oral anticoagulants (95% DOAC, 5% warfarin), the sub-analysis of 1,600 patients with atrial fibrillation who underwent a device implantation either concomitantly or sequentially (90-180 days post ablation) demonstrated:

- Consistent with the previously presented primary safety and efficacy endpoint data presented in November 2024, concomitant LAAC with the WATCHMAN FLX device following an ablation demonstrated a statistically significant 44% reduction in non-procedural bleeding outcomes compared to OAC at 36 months (8.0% vs. 13.3%; p=0.02) and similar efficacy outcomes (7.0% vs. 6.7% p=0.91), with the primary efficacy endpoint defined as all-cause death, stroke or systemic embolism.
- Also consistent with the previously presented primary safety and efficacy endpoint data, sequential LAAC with the WATCHMAN FLX device following an ablation demonstrated a statistically significant 62% reduction in non-procedural bleeding outcomes compared to OAC at 36 months (8.8% vs. 21.5%; p<0.0001) and similar efficacy outcomes (4.2% vs.

5.3%; p=0.45).

- Similar stroke protection with the WATCHMAN FLX device compared to OAC irrespective of concomitant (2.3% vs. 2.5% rates of all stroke) or sequential (1.1% vs 1.6%) implantation.

"These late-breaking studies provide valuable clinical evidence supporting our ablation and stroke prevention technologies that are designed to improve long-term outcomes for patients with atrial fibrillation," said Dr. Brad Sutton, M.D., chief medical officer, Atrial Fibrillation Solutions, Boston Scientific. "The positive findings support our focus on expanding the number of patients who can benefit from these life-changing therapies, which we will continue to advance through future clinical trials and product development."

More information on the ADVANTAGE AF study is availablehere and on the OPTION trial here.***

About Boston Scientific
Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. 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.

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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: future economic, competitive, reimbursement and regulatory conditions; 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; 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 beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System.

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

press release.

*** The FARAPULSE PFA System was not commercially available at the time of the OPTION trial initiation and was not included in the trial design.

[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

[2] Wazni OM, Saliba WI, Nair DG, et al. Left atrial appendage closure after ablation for atrial fibrillation.*N Engl J Med*. 2024 Nov 16. doi:10.1056/NEJMoa2408308

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https://news.bostonscientific.eu/2025-01-16-Late-breaking-data-presented-at-AF-Symposium-2025-highlight-key-Boston-Scientific-therapies-for-management-of-patients-with-atrial-fibrillation