Boston Scientific

CHAMPION-AF study of the WATCHMAN FLX™ Left Atrial Appendage Closure Device as a first-line therapy for stroke risk reduction meets all primary and secondary safety and efficacy endpoints

Data highlights the WATCHMAN FLX device provided statistically superior protection from bleeding, demonstrated similar efficacy compared to blood thinners in patients with non-valvular atrial fibrillation

Late-breaking findings presented at ACC.26 and simultaneously published in The New England Journal of Medicine

MARLBOROUGH, Mass. and NEW ORLEANS, March 28, 2026 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the CHAMPION-AF global clinical trial met all primary and secondary safety and efficacy endpoints. The study evaluated the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device compared to non-vitamin K antagonist oral anticoagulants (NOACs) as a first-line option for stroke risk reduction in a broad population of patients with non-valvular atrial fibrillation (NVAF). Key results were presented as a late-breaking clinical trial at the American College of Cardiology's Annual Scientific Session & Expo and simultaneously published in ***The New England Journal of Medicine***

Atrial fibrillation (AF) is an increasingly common heart rhythm disorder that affects approximately 59 million people worldwide[1] and increases stroke risk by five times compared to people with a normal heart rhythm.[2] In patients with NVAF, more than 90% of heart-related blood clots form in the left atrial appendage (LAA).[3] An alternative to long-term NOACs – considered the leading contemporary blood thinners for stroke risk reduction in patients with NVAF – the WATCHMAN technology is designed to permanently close off the LAA and is implanted in a single procedure.

"The success of the landmark CHAMPION-AF trial represents a meaningful milestone that will undoubtedly transform the treatment approach to stroke risk reduction in a broader population of patients who historically have needed to rely on medication," said Martin Leon, M.D., study co-chair and Mallah Family professor of cardiology, chief innovation officer and director, Cardiovascular Data Science Center, Columbia University Medical Center.* "These results should give clinicians confidence in the potential of the WATCHMAN FLX device to become a first-line treatment option for reducing the risk of stroke for a rapidly growing number of patients with AF."

The randomized, controlled trial enrolled 3,000 patients with NVAF who were suitable for oral anticoagulation therapy across a broad spectrum of stroke and bleeding risk. At 36 months:

- The primary safety endpoint was met with data demonstrating the WATCHMAN FLX device was statistically superior to NOACs (10.9% vs. 19.0%; P<0.001) for non-procedural major and clinically relevant non-major bleeding, achieving a 45% relative reduction in non-procedural bleeding risk.
    - When including procedural bleeding in a secondary analysis, the WATCHMAN FLX device performance was consistent with the primary safety endpoint, demonstrating a significant reduction in bleeding compared to NOACs (12.8% vs. 19.0%; P<0.001) for major and clinically relevant non-major bleeding, representing a 34% relative reduction in procedural and non-procedural bleeding risk.

- The primary efficacy endpoint, defined as occurrence of stroke, cardiovascular or unexplained death or systemic embolism, was met with the WATCHMAN FLX device achieving statistical non-inferiority compared to NOACs (5.7% vs. 4.8%; P<0.001).

The study's secondary safety endpoint underscored the WATCHMAN FLX device is statistically non-inferior to NOACs at 36 months for procedural and non-procedural major bleeding (5.9% vs. 6.4%; P<0.001). Additionally, a secondary combined safety and efficacy endpoint highlighted a net clinical benefit with the device demonstrating statistical superiority to NOACs for the occurrence of cardiovascular death, stroke, systemic embolism and non-procedural major bleeding and clinically relevant non-major bleeding (15.1% vs. 21.8%; P<0.001).

CHAMPION-AF is the largest clinical trial comparing an LAAC device to NOACs for patients with NVAF to date and included 141 sites in the U.S., Canada, Europe, Japan and Australia, which implanted the devices with a 99% procedural success rate. Patient follow-up in the CHAMPION-AF trial will continue through five years and will include additional primary and secondary endpoints.

"These positive data, which have the potential to support updated clinical guidelines globally, will be used in our submission to expand the indication and coverage for the well-established WATCHMAN platform as a first-line stroke risk reduction option, providing physicians with more choices in care for a wider range of patients who have atrial fibrillation," said Brad Sutton, M.D., chief medical officer, Atrial Fibrillation Solutions, Boston Scientific. "Today, 40% of patients with AF who are prescribed blood thinners for stroke risk reduction are not taking their medications consistently, significantly increasing their risk of stroke.[4] The CHAMPION-AF data add to Boston Scientific's robust body of clinical evidence supporting the WATCHMAN device as a one-

time implant that helps provide stroke risk protection over a patient's lifetime."

More than 600,000 people have been treated with the WATCHMAN implant, which is the most implanted and studied LAAC device on the market. The WATCHMAN LAAC device was first introduced to the European market in 2009 and was approved by the U.S. Food and Drug Administration (FDA) in 2015. The latest-generation WATCHMAN FLX™ Pro LAAC Device was approved in the U.S. in 2023 and is currently being studied in several clinical trials, including the SIMPLAAFY randomized controlled trial, which is evaluating single-drug alternatives to dual anti-platelet therapy as a post-procedural regimen.

For more information about the CHAMPION-AF trial, visitwatchman.com/CHAMPION

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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, product performance and impact, clinical trials, and new and anticipated product approvals and/or indications or coverage expansions. 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, conflicts and tensions; 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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[1] Linz, Dominik, et al. Atrial fibrillation: epidemiology, screening and digital health. Lancet Reg Health Eur. 2024 Feb 1:37:100786. https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(23)00205-3/fulltext. Accessed Feb. 3, 2026.

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