Boston Scientific

SIMPLAAFY study of the WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device meets primary endpoints

Both post-implant monotherapies in the trial achieved non-inferiority compared to dual anti-platelet therapy (DAPT) supporting the potential to simplify post-procedure drug regimens

MARLBOROUGH, Mass. and SAN DIEGO, Nov. 2, 2026 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive six-month primary endpoint results from the SIMPLAAFY randomized controlled trial of the WATCHMAN FLX™ Pro Left Atrial Appendage Closure (LAAC) Device. The study evaluated two single-drug regimens as alternatives to dual anti-platelet therapy (DAPT) following implantation of the device in patients with non-valvular atrial fibrillation (NVAF). Key results were presented as a late-breaking clinical trial at Transcatheter Cardiovascular Therapeutics® (TCT®) 2026, the annual scientific symposium of the Cardiovascular Research Foundation® (CRF®) and simultaneously published in ***JAMA***.

The WATCHMAN FLX Pro device used in the trial is intended to protect against strokes caused by blood clots that form in the left atrial appendage (LAA) in people with NVAF who need an alternative to long-term blood thinners, and includes HEMOCOAT Technology™, which is designed to enable more controlled, faster healing following implantation. The SIMPLAAFY trial is assessing whether the device, with the addition of HEMOCOAT, may continue to offer similar rates of stroke protection and reduce early bleeding when paired with less-intensive post-implant regimens, and will follow patients through 12 months.

"For patients with NVAF who undergo an LAAC procedure, balancing short-term bleeding risk with the need to maintain stroke protection during post-procedure healing is critical," said Saibal Kar, M.D., study co-chair and director, Structural Heart Disease Interventions and Clinical Research, Los Robles Health System.* "The findings from the SIMPLAAFY trial are encouraging and highlight the potential to meaningfully simplify post-procedure care and reduce medication burden for patients following WATCHMAN FLX Pro implantation."

The study randomized 1,857 patients across 86 clinical study sites in the U.S. to a post-implant regimen of aspirin alone for the duration of the trial or reduced-dose non-vitamin K antagonist oral anticoagulant (NOAC) for the first three months followed by aspirin only or a DAPT regimen of aspirin and clopidogrel antiplatelet medication for the first six months, followed by aspirin only. At six months, data demonstrated that the aspirin alone and reduced-dose NOAC alone regimens each achieved noninferiority to DAPT, with patients on these regimens experiencing less bleeding and equivalent ischemic stroke rates to DAPT (0.7%). Additionally, imaging at 45 days also showed the rate of device-related thrombus, or clotting, was lowest in the patients on a reduced-dose NOAC compared to DAPT (0.9% vs. 3.4%; P=0.01).

"Innovation in LAAC extends beyond device technology to advancing the therapy through improved care delivery and an enhanced experience for physicians and patients," said Brad Sutton, M.D., chief medical officer, Atrial Fibrillation Solutions, Boston Scientific. "The SIMPLAAFY trial provides valuable clinical evidence that can help physicians make more informed decisions about post-implant care and tailor treatment to individual patient needs. Together with advancements like HEMOCOAT Technology, these findings represent meaningful progress toward simplifying treatment and advancing care for patients with atrial fibrillation."

With more than two decades of clinical evidence, the WATCHMAN implant has helped reduce stroke risk for more than 800,000 patients worldwide. The current-generation WATCHMAN FLX Pro device was approved by the U.S. Food and Drug Administration in 2023. Enrollment in the Elite AF trial, evaluating the safety and efficacy of the next-generation WATCHMAN Elite™ LAAC Device, commenced in 2026.

For more information about the SIMPLAAFY trial, visitwatchman.com/SIMPLAAFY.

Caution: Aspirin alone or reduced dose NOAC alone following LAAC with the WATCHMAN FLX Pro LAAC Device is an investigational post-implant drug regimen.

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 healthcare. 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 follow us on **LinkedIn** .

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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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