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Boston Scientific WATCHMAN FLX™ Left Atrial Appendage Closure Device demonstrates superior bleeding risk reduction to oral anticoagulation following a cardiac ablation in the OPTION clinical trial

Data also demonstrates that the stroke risk reduction device is as effective as oral anticoagulants for patients with atrial fibrillation following a cardiac ablation

MARLBOROUGH, Mass. and CHICAGO, Nov. 16, 2024 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive three-year primary endpoint results from the OPTION global clinical trial of the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device. Key findings from the study comparing the device to first-line oral anticoagulation (OAC) – including direct oral anticoagulants (DOAC) (95%) and warfarin (5%) – for stroke risk reduction in patients with non-valvular atrial fibrillation following a cardiac ablation were presented in a late-breaking science session at the American Heart Association's Scientific Sessions 2024, and simultaneously published in *The New England Journal of Medicine*.

The trial met the primary safety endpoint of non-procedural major bleeding or clinically relevant non-major bleeding at 36 months, with the WATCHMAN FLX device demonstrating superiority to OAC (8.5% vs.18.1%; P<0.0001). It also met the primary efficacy endpoint of all-cause death, stroke or systemic embolism at 36 months, with the data showing non-inferiority of the device to OAC (5.4% vs. 5.8%; P<0.0001). Additional findings included non-inferiority of the WATCHMAN FLX device for the combined secondary endpoint of procedural and non-procedural major bleeding at 36 months (3.9% vs. 5.0%; P<0.0001).

In recent years, the number of patients with atrial fibrillation who have undergone a cardiac ablation procedure to prevent symptoms has grown significantly. Due to the risk of atrial fibrillation recurrence following an ablation, current treatment guidelines recommend that patients with multiple stroke risk factors remain on OAC long term to reduce the risk of stroke. However, symptomatic relief can lead these patients to stop taking their blood thinners, increasing this risk, while long-term use of OAC also presents a risk of serious bleeding.

"The OPTION trial data provide clinical evidence indicating that, among patients who have undergone an ablation, LAAC with the WATCHMAN FLX device is not only as safe, but superior to OAC therapy for reducing the risk of long-term bleeding events," said Dr. Oussama Wazni, vice chairman of Cardiovascular Medicine and section head, Cardiac Electrophysiology, Cleveland Clinic, and principal investigator of the OPTION trial.* "Notably, we found high rates of procedural success in patients who had a WATCHMAN FLX implant after an ablation, and of patient adherence to their prescribed medication regimen following the procedures, which likely reinforced positive outcomes such as the low rates of ischemic and hemorrhagic stroke within the trial population."

The randomized, controlled OPTION trial included 1,600 patients enrolled across 114 sites inthe United States, Europe and Australia, and demonstrated high rates of procedural success. In the trial, approximately 60% of device patients had their WATCHMAN FLX implant 90-180 days following their ablation procedure. The other nearly 40% of the device patients had the two procedures performed concomitantly, with the WATCHMAN FLX implant taking place after the ablation.

"The OPTION trial is the first large, randomized trial to rigorously evaluate LAAC as a safe and effective stroke risk reduction treatment following a cardiac ablation in a head-to-head fashion against commonly used oral anticoagulants, including DOAC," said Brad Sutton, M.D., chief medical officer, Atrial Fibrillation Solutions, Boston Scientific. "These positive primary outcomes mean that patients receiving the WATCHMAN FLX device were able to eliminate long-term medication use while maintaining stroke protection. With this data, we see potential to both expand the indication for the WATCHMAN FLX platform and ultimately elevate it to become a frontline therapy for patients receiving cardiac ablation for atrial fibrillation to reduce their risk of stroke."

In addition to the OPTION trial, the WATCHMAN technology is being evaluated against DOAC as a first-line therapy in lower-risk patients within the CHAMPION-AF randomized trial. The latest-generation WATCHMAN FLX™ Pro LAAC Device, which was approved in the United States in 2023, is similarly being studied in several clinical trials, including the SIMPLAAFY randomized controlled trial that is evaluating a single-drug alternative to dual anti-platelet therapy as a post-procedural regimen.

For more information on the OPTION trial, visithttps://www.watchman.com/en-us-implanter/clinical-evidence/option.html.

About Boston Scientific
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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.

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

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