Boston Scientific

Boston Scientific Announces FDA Approval for the Latest-Generation WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device

New stroke risk reduction therapy with thromboresistant coating is designed to advance procedural performance and safety

MARLBOROUGH, Mass., Sept. 6, 2023 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received U.S. Food and Drug Administration approval for the latest-generation WATCHMAN FLX™ Pro Left Atrial Appendage Closure (LAAC) Device. Designed to further advance the procedural performance and safety of the WATCHMAN technology, which is indicated to reduce stroke risk in patients with non-valvular atrial fibrillation (NVAF) who need an alternative to oral anticoagulation therapy, the device now features a polymer coating, visualization markers and a broader size matrix to treat a wider range of patients.

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The WATCHMAN FLX Pro device is built upon the proven safety and procedural performance of the WATCHMAN FLX™ LAAC device, which was approved in July 2020 and has been used in nearly 190,000 of the more than 300,000 WATCHMAN procedures successfully completed to date globally. The latest WATCHMAN FLX Pro device is enhanced with a coating designed to reduce device-related thrombus and enable faster, controlled healing and endothelization of the device surface. In addition, newly added visualization markers are intended to enhance device placement for optimal sealing around the LAA. This device is also available in a new 40mm size option, which will enable physicians to treat a broader range of anatomies with the WATCHMAN technology.

"We are pleased to introduce U.S. clinicians to our newest LAAC technology, which is designed to enhance post-procedural healing, improve the precision of WATCHMAN FLX Pro implants, and expand the size range of treatable appendages," said Joe Fitzgerald, group president, Cardiology, Boston Scientific. "These enhancements to our WATCHMAN FLX technology will enable efficiency during implant procedures and allow physicians to optimize treatment for their patients."

Preclinical research for the new technology has shown positive results for faster, more controlled healing around the device surface. Data across several of these preclinical studies demonstrated that the polymer coating provided an 86% reduction in inflammation three days following the procedure, a 70% reduction of thrombus at 14 days and a 50% increase in endothelial tissue coverage 45 days post procedure.[1]

"There is a rich history of safe use and low thrombosis rates in cardiovascular devices that utilize this thromboresistant polymer coating, and we have adapted that model to provide a more streamlined healing process that begins immediately following LAAC," said Dr. Kenneth Stein, M.D., senior vice president and global chief medical officer, Boston Scientific. "We believe this evolution of the WATCHMAN device also gives promise for a future with less thrombosis risk, which may eventually enable a simpler post-implant drug regimen for patients."

The WATCHMAN FLX Pro device maintains key characteristics of the WATCHMAN FLX device, including the fully rounded design that enables physicians to safely enter, and maneuver within, the left atrial appendage. It can also be fully recaptured, repositioned and redeployed for precise placement, and the frame design allows for optimal device engagement with the tissue for long-term stability and a faster, more complete seal.

The WATCHMAN FLX Pro device is currently being studied in the WATCHMAN FLX Pro CT study, a single-center premarket study using multiple imaging modalities to assess post-procedural device tissue coverage and the relationship, if any, to clinical outcomes. It will also be further evaluated in the post-market HEAL-LAA study, which will commence over the coming weeks and follow outcomes from approximately 1,000 patients with NVAF implanted with the technology at 60 sites in the U.S.

For more information on the WATCHMAN FLX Pro device, visit www.watchman.com/flxpro.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 40 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. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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," "may," "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, new and anticipated product approvals and launches, and clinical trials. 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 global economic, political, competitive, reimbursement and regulatory conditions; new product introductions; expected procedural volumes; demographic trends; intellectual property; litigation; financial market conditions; execution and effect of our business strategy; 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. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[1] Saliba et al. JACC: Clinical Electrophysiology, May 2023.

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