Boston Scientific

Late-Breaking Study Results Reinforce Positive Real-World Outcomes with the WATCHMAN FLX™ LAAC Device

MARLBOROUGH, Mass., Feb. 28, 2022 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive results from a new analysis assessing real-world outcomes with the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device. Presented during a late-breaking trial session at the Cardiovascular Research Technologies (CRT) 2022 meeting, the SURPASS analysis included data from more than 16,000 patients with non-valvular atrial fibrillation within the National Cardiovascular Data Registry (NCDR) Left Atrial Appendage Occlusion (LAAO) Registry.

The positive data demonstrated a low 0.37% rate of major adverse events at seven days following a WATCHMAN FLX implant or the time of hospital discharge, whichever was later. This key safety endpoint was defined as a composite of all-cause death, ischemic stroke, systemic embolism or device/procedure-related events requiring open cardiac surgery or major endovascular intervention. Additional outcomes measured at the 45-day follow up after a WATCHMAN FLX implant included a 0.51% rate of pericardial effusion requiring either surgical or percutaneous intervention, with only 0.03% of patients requiring cardiac surgery.

"This analysis includes the largest number of real-world WATCHMAN FLX patients to date and provides evidence that this stroke reduction therapy is associated with a low incidence of adverse events and peri-device leak through 45 days," said Dr. Samir Kapadia, chairman of the Robert and Suzanne Tomsich Department of Cardiovascular Medicine, Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute, Cleveland Clinic.[1] "SURPASS represents the experience of more than 2,000 physicians using this therapy in routine clinical practice."

In the analysis, the WATCHMAN FLX device was successfully implanted in 97.6% of patients, and data also demonstrated low rates of ischemic stroke (0.28%) and device embolization (0.03%) in patients at 45 days. The SURPASS study is ongoing and will continue to collect outcomes through at least two years post-implant on all patients in the NCDR-LAAO Registry treated with WATCHMAN FLX between August 2020 and August 2022. The key effectiveness endpoint of occurrence of ischemic stroke or systemic embolism will be evaluated after 24 months.

"The strong safety and efficacy profile of the WATCHMAN FLX device demonstrated in the SURPASS analysis reinforces many of the safety and effectiveness results seen in the pivotal PINNACLE FLX trial, while representing a high-risk, real-world patient population and wide variety of patient anatomies," said Dr. Ian Meredith, global chief medical officer, Boston Scientific. "We look forward to further analyses from this large, representative study of patients with NVAF treated by physicians with a broad range of implanting experience."

The WATCHMAN technology has been implanted in more than 200,000 patients worldwide, with clinical research on the use of the WATCHMAN FLX device in patients with NVAF continuing via two large prospective, randomized controlled trials: the OPTION and CHAMPION-AF clinical studies.

For more information, visit www.watchman.com/implanter.

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," "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, clinical trials and product performance and impact. 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; new product introductions; 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. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[1] *Dr. Samir Kapadia has not been compensated by Boston Scientific Corporation for his work on the SURPASS analysis or his quote within this news release.*

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https://stage.mediaroom.com/bostonscientific/2022-02-28-Late-Breaking-Study-Results-Reinforce-Positive-Real-World-Outcomes-with-the-WATCHMAN-FLX-TM-LAAC-Device