Boston Scientific

Late-Breaking Trial Data at TVT Demonstrate Sustained Safety and Performance of WATCHMAN FLX™ Left Atrial Appendage Closure Device

PINNACLE FLX study meets 24-month endpoint, reinforces positive 12-month outcomes with next-generation device for patients with non-valvular atrial fibrillation

MARLBOROUGH, Mass., July 21, 2021 /PRNewswire/ -- Today, Boston Scientific (NYSE: BSX) announced positive 24-month results from the PINNACLE FLX clinical trial assessing the safety and efficacy of the next-generation WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device for patients with non-valvular atrial fibrillation (NVAF). Presented as late-breaking clinical science at TVT: The Structural Heart Summit, the study evaluated the WATCHMAN FLX device as an alternative to long-term oral anticoagulation therapy, including non-vitamin K antagonist oral anticoagulants (NOACs), for stroke risk reduction in patients with NVAF.

The prospective, non-randomized PINNACLE FLX trial included 400 patients in the U.S. with NVAF who were eligible for anti-coagulation therapy to reduce the risk of stroke but had appropriate rationale to seek a non-pharmaceutical alternative. Following the positive 12-month results in which the trial met its primary safety and efficacy endpoints, the trial met its secondary effectiveness endpoint – defined as the occurrence of ischemic stroke or systemic embolism over 24 months – with a rate of 3.4% compared to the performance goal of 8.7%.[1]

"These findings demonstrate sustained device performance over two years and reinforce the excellent safety and efficacy profile of the WATCHMAN FLX technology," said Saibal Kar, M.D., study co-principal investigator and interventional cardiologist at Los Robles Regional Medical Center and Bakersfield Heart Hospital, California. "Building upon the low complication rates and 100% rate of effective LAA closure seen at 12 months, the 3.4% rate of ischemic stroke and systemic embolism at 24 months is very encouraging in this complex, elderly patient population."

In addition to the low rate of ischemic stroke, the data through 24 months also demonstrated that no patients experienced a device embolization or pericardial effusion requiring cardiac surgery, all of which is favorable in the context of previous clinical studies.[2]

"The final results of this pivotal study underscore how design advancements of the WATCHMAN FLX device – which allow for improved anchoring, a faster, more effective LAA closure and compatibility with more complex anatomies – have translated into a safe, effective and durable option for patients with NVAF at increased risk for stroke and systemic embolism and an appropriate rationale to seek a non-pharmaceutical alternative," said Dr. Ian Meredith, AM, global chief medical officer, Boston Scientific.

The next-generation WATCHMAN FLX device received U.S. Food and Drug Administration (FDA) approval in July 2020 and CE Mark in March 2019, and is now used in nearly all implants in the U.S. and Europe in lieu of the previous-generation device.

The company continues its clinical research on the WATCHMAN FLX device for use in patients with NVAF via two large prospective, randomized controlled trials: the OPTION trial – comparing the WATCHMAN FLX device to oral anticoagulants in patients who also undergo a cardiac ablation procedure; and the CHAMPION-AF clinical trial – studying a broader anticoagulant-eligible patient population to evaluate the device against NOACs for embolic stroke prevention.

For more information on the WATCHMAN FLX device, 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] By Kaplan-Meier estimate

[2] Kar, S. Primary Outcome Evaluation of a Next Generation Left Atrial Appendage Closure Device: Results from the PINNACLE FLX Trial, Circulation, 2021.

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https://news.bostonscientific.com/2021-07-21-Late-Breaking-Trial-Data-at-TVT-Demonstrate-Sustained-Safety-and-Performance-of-WATCHMAN-FLX-TM-Left-Atrial-Appendage-Closure-Device