Boston Scientific

Boston Scientific Receives FDA Approval for Next-Generation WATCHMAN FLX™ Left Atrial Appendage Closure Device

New stroke risk reduction technology designed to advance procedural performance and safety, treat wider range of patients with non-valvular atrial fibrillation

MARLBOROUGH, Mass., July 21, 2020 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced it has received U.S. Food and Drug Administration (FDA) approval for the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device.

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The next-generation WATCHMAN FLX device is indicated to reduce the risk of stroke in patients with non-valvular atrial fibrillation (NVAF) who need an alternative to oral anticoagulation therapy by permanently closing off the left atrial appendage – the area of the heart where stroke-causing blood clots commonly form in NVAF. This technology, which is built upon the most studied and implanted LAAC device in the world, features a new, fully rounded design that offers physicians the ability to safely enter, and maneuver within, the left atrial appendage. It is the first LAAC device that can be fully recaptured, repositioned and redeployed for precise placement, and the new frame design allows for optimal device engagement with the tissue for long-term stability and a faster, more complete seal. The WATCHMAN FLX device is available in broader size options than the previous generation device and can treat a wider range of patient anatomies.

"We've been very pleased with the real-world clinical outcomes and positive physician feedback for the WATCHMAN FLX device in Europe and are excited to extend availability of this next-generation technology to patients and clinicians throughout the U.S.," said Joe Fitzgerald, president, Interventional Cardiology, Boston Scientific. "Our WATCHMAN technology was the first FDA-approved LAAC device on the market and has been implanted in more than 100,000 patients worldwide, and now with the WATCHMAN FLX device, we are taking the clinical benefits of the technology to the next level for more patients while further differentiating our structural heart portfolio in the U.S."

Positive 12-month results from the pivotal PINNACLE FLX study, which evaluated the performance of the WATCHMAN FLX device as an alternative to long-term non-vitamin K antagonist oral anticoagulants (NOACs) and other OAC medications, were recently presented as a late-breaking clinical trial at Heart Rhythm Society 2020 Science. The study met its primary safety and efficacy endpoints with data demonstrating a low rate of major procedure-related safety events (0.5% at 7 days post procedure) and high rate of effective LAAC (100% with peri-device flow ≤ 5mm at 12 months post procedure). Data also demonstrated a high implant success rate of 98.8%.

"Built upon the success of the WATCHMAN platform and thousands of patient-years of clinical research, the next-generation WATCHMAN FLX device is designed to offer increased ease of use for physicians and improved procedural outcomes for patients, including reduced complication risk and healing time," said Dr. Ian Meredith, AM, global chief medical officer, Boston Scientific. "We've set the bar high and look forward to bringing these benefits to a wider range of U.S. patients with NVAF who need an alternative to the bleeding risk and lifestyle challenges associated with long-term use of blood thinners."

Additional clinical research using the WATCHMAN FLX device for patients with NVAF will continue via enrollment in the OPTION trial – comparing the device to oral anticoagulants in patients who also undergo a cardiac ablation procedure – as well as in the CHAMPION-AF trial, which will study a broader OAC-eligible patient population in a head-to-head fashion to compare the device against NOACs.

The company announced CE Mark for the next-generation WATCHMAN FLX device inMarch 2019 and will immediately commence a limited launch of the device in the U.S.

For more information on the WATCHMAN FLX device, visitwww.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 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 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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