Boston Scientific

Boston Scientific Announces Positive European Registry Results For WATCHMAN™ Left Atrial Appendage Closure Device

Largest Prospective Study of the WATCHMAN Device Presented as Late-Breaking Trial at Heart Rhythm 2017

MARLBOROUGH, Mass., May 12, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced positive safety and efficacy rates of the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device from the EWOLUTION registry presented during a late-breaking clinical trial session at Heart Rhythm 2017, the Heart Rhythm Society's 38th Annual Scientific Sessions in Chicago. Data confirmed that the WATCHMAN device had a high implant success rate and was effective in stroke reduction for patients with non-valvular atrial fibrillation (AF), including those patients deemed unsuitable for oral anticoagulation.

The prospective, single-arm, multicenter EWOLUTION registry evaluated 1,025 patients with non-valvular AF who have a high risk for stroke and systemic embolism. At one year post implantation of the device, the results demonstrated an 84 percent reduction in the annual stroke rate (1.1 vs 7.2/100 pt-years) as compared to predicted rates of untreated patients with similar risk profile and a reduction of 48 percent in the annual rate of major bleeding (2.6 vs 5.0/100 pt-years) as compared to predicted rates for patients treated with warfarin.*

"This impressively low ischemic stroke rate favors left atrial appendage closure as an important therapy for patients ineligible for long-term oral anticoagulation," said Lucas V.A. Boersma, M.D., Ph.D., study principal investigator and electrophysiologist at St. Antonius Hospital, the Netherlands. "The results further validate the utility of the WATCHMAN device as an excellent alternative to anticoagulant therapy and its related bleeding risks for patients with non-valvular AF."

In the study, patients were enrolled at 47 centers throughout Europe, Russia and the Middle East. More than 70 percent of the patients were deemed unsuitable for short or long-term anticoagulation at the time of WATCHMAN implantation. Transient ischemic attacks, ischemic stroke, vascular disease and a history of major bleeding were present in approximately half of the patients.

"We are pleased to see that these 'real-world' results reinforce the positive outcomes observed in our clinical trial program, despite the registry patients being older and sicker than those enrolled in our previous trials," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific.

Additional EWOLUTION data will be presented on May 18 at the annual EuroPCR Scientific Congress in Paris.

The WATCHMAN device was CE-marked in 2005 to prevent thrombus embolization from the left atrial appendage and reduce the risk of life-threatening bleeding events in patients with non-valvular AF who are eligible for anticoagulation therapy, and in 2012 the CE Mark indication was expanded to include those who have a contraindication to anticoagulation therapy. In 2015, the device received FDA approval for patients with non-valvular AF who are at high stroke risk, suitable for warfarin and are seeking an alternative to long-term warfarin therapy. The Centers for Medicare and Medicaid Services (CMS) began covering percutaneous LAAC therapy for Medicare beneficiaries in February 2016 when patients meet the specific criteria outlined in the agency's final National Coverage Determination (NCD).

For more information on the WATCHMAN device, visit www.watchman.com.

*CHA2DS2 VASc and HAS-BLED scores have been validated to predict annual rates of ischemic stroke and bleeding, respectively. In order to provide context for the results given the absence of a control group, analyses were performed to compare EWOLUTION event rates to these historical rates for patients of a similar risk profile.

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 35 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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