# Boston Scientific WATCHMAN™ Left Atrial Appendage Closure Device Receives CE Mark Approval For Expanded Use

Newly Revised European Society of Cardiology Guidelines Include LAA Closure Devices

European regulators have approved an expanded indication for the Boston Scientific Corporation (NYSE: BSX) WATCHMAN® Left Atrial Appendage (LAA) Closure Device. The new indication offers patients with atrial fibrillation (AF), and a contraindication to warfarin and the newer oral anticoagulants, a new treatment option for stroke reduction.

Atrial fibrillation affects approximately 15 million patients worldwide and is a disorder that disrupts the ability of the heart to beat regularly and pump blood efficiently. Patients in AF have an increased risk of stroke due to the migration of clots formed in the LAA. Blood-thinning medications have previously been the only therapy for reducing stroke risk in these patients.

This CE Mark approval of the WATCHMAN device was based on results from the ASAP study. WATCHMAN is a novel device introduced into the heart via a flexible tube (catheter) through a vein in the groin intended to close off the LAA. The device is designed to capture any clots that may form in the appendage, reducing the risk of stroke and potentially eliminating the need for long term use of blood thinning medications.

"The expanded indication for WATCHMAN represents a significant advance for these patients who are at high risk of stroke, but who are unable to take conventional anticoagulant therapy," said Kenneth Stein, M.D., chief medical officer of Boston Scientific's Cardiac Rhythm Management Group. "WATCHMAN continues to demonstrate that it is an effective therapy for preventing stroke in patients with atrial fibrillation."

In addition, the European Society of Cardiology (ESC) today announced the inclusion of LAA closure devices in the revised "Guidelines for Management of Patients with Atrial Fibrillation." The recommendation was based on the expansive WATCHMAN LAA closure device clinical data, collected on more than 2,000 patients and exceeded the equivalent of 4,000 patient years of follow up across multiple studies. These studies include the PROTECT AF trial, which proved the WATCHMAN device was non-inferior to warfarin and demonstrated a 38 percent relative risk reduction for stroke, cardiovascular death and systemic embolism compared to long-term warfarin therapy; the ASA Plavix (ASAP) Registry, which demonstrated a 77 percent reduction for ischemic stroke in patients contraindicated to warfarin; and the Continued Access PROTECT AF trial, which demonstrated improved procedural outcomes with experience.

The WATCHMAN device was approved for use in Europe in 2005 and some countries in Asia in 2009. Boston Scientific recently completed enrollment in the PREVAIL study, a confirmatory study designed to gain U.S. Food and Drug Administration approval. Patient follow up for the study is six months. In the U.S., the WATCHMAN device is an investigational device, limited by applicable law to investigational use and not available for sale. The device was developed by Atritech, which Boston Scientific acquired in March 2011. Please visit https://www.bostonscientific.com/watchman for more information.

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About Boston Scientific
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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, markets for our products, clinical trials and the importance of trial results, product performance and impact, and competitive offerings. 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

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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.

[1]For Bayesian analysis, posterior probabilities are used to determine superiority; > 95% represents superiority



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