Boston Scientific

The Boston Scientific Watchman® Device Continues To Demonstrate Positive Clinical Outcomes For Patients With Atrial Fibrillation

NATICK, Mass., March 9, 2013 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) reports preliminary data in the PREVAIL clinical trial met two out of three co-primary endpoints.

The PREVAIL trial evaluates safety and efficacy of the WATCHMAN® Left Atrial Appendage (LAA) Closure device in patients with nonvalvular atrial fibrillation versus long-term warfarin therapy. The device is designed to close off the LAA, a major source of clots in patients with atrial fibrillation, and reduce the risk of stroke, potentially eliminating the need for long-term use of blood-thinning medications.

The prospective, randomized PREVAIL trial enrolled 407 patients at 41 sites and compared the WATCHMAN device to warfarin in high-risk patients with nonvalvular atrial fibrillation eligible for long-term warfarin therapy. PREVAIL builds on data from the PROTECT AF clinical trial which enrolled 707 randomized patients treated with either the WATCHMAN device or standard warfarin therapy to evaluate the safety and effectiveness of the WATCHMAN technology. The PREVAIL trial was designed to confirm the results of the PROTECT AF trial and validate the safety of the implant procedure, including at least 25 percent of subjects treated by new operators.

Preliminary Results
The PREVAIL trial met the pre-specified criteria for the first co-primary endpoint of occurrence of all-cause death, ischemic stroke, systemic embolism, or device or procedure-related events requiring open cardiac surgery or major endovascular intervention (randomization to seven days post procedure or by hospital discharge, whichever is later). The trial did not meet the pre-specified criteria for the second co-primary endpoint of the occurrence of all stroke (ischemic or hemorrhagic), cardiovascular death and systemic embolism at 18 months. While the second co-primary efficacy endpoint was not met, the device performed similar to warfarin with a rate ratio of 1.07. The PREVAIL trial met its pre-specified endpoint for the third co-primary endpoint of the composite of the occurrence of late ischemic stroke and systemic embolism (eight days post randomization and onward) at 18 months. The reported endpoint results are preliminary and require final validation.

Specifically, safety data demonstrated an increase in implant success rate overall (95.0 percent), and with new operators (93.2 percent), compared to PROTECT AF (90.9 percent). The overall seven-day serious procedure/device related complication rate was 4.4 percent in PREVAIL vs. 8.7 percent in PROTECT AF, a 49 percent relative reduction. A key result of the PREVAIL trial was that pericardial effusions requiring intervention occurred at a rate comparable to other left atrial procedures. PREVAIL reported a 1.9 percent event rate vs. 4.0 percent in PROTECT AF, a 52 percent relative reduction. Additionally, new operators had only one occurrence (1.0 percent) of pericardial effusion requiring intervention with no device embolization, peri-procedural strokes or cardiac perforation.

"The results of the PREVAIL trial add to the wealth of previously published data confirming the utility of the WATCHMAN device as an option for the reduction of stroke in high risk patients," said Kenneth Stein, M.D., chief medical officer, Cardiac Rhythm Management, Boston Scientific. "WATCHMAN is the only device-based alternative to anticoagulation that has undergone rigorous scientific study. We are pleased the PREVAIL results showed low complication rates with both new and experienced operators and significantly lower complications than the early stage of the PROTECT AF trial."

Data from the PREVAIL trial, complemented by the PROTECT AF four-year outcomes data, the WATCHMAN Pilot study six-year data, the ASAP study and the CAP registry data update will be submitted to support device approval by the U.S. Food and Drug Administration (FDA).

The WATCHMAN device was approved for sale in Europe in 2005 and some countries in Asia in 2009. It is already commercially available in 40 countries worldwide. In the United States, WATCHMAN 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 http://www.bostonscientific.com/PREVAIL for more information. Images of the WATCHMAN device are available for download at http://bostonscientific.mediaroom.com/image-gallery?mode=gallery&cat=1760.

Atrial fibrillation (AF) affects approximately 15 million patients worldwide and is a disorder that disrupts the ability of the heart to beat regularly and pump blood efficiently. AF patients have a five times greater risk of stroke. Blood-thinning medications have previously been the only therapy for reducing stroke risk in these patients. Boston Scientific offers an alternative to chronic medication. The WATCHMAN device is introduced into the heart via a flexible tube (catheter) through a vein in the groin and closes off the LAA.

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 regulatory submissions and approvals, clinical trials and the impact of their results, product performance 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 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; final clinical trial results; 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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