Boston Scientific

Boston Scientific Completes Patient Enrollment in PREVAIL Study for First-in-Class WATCHMAN Device

Milestone Marks Next Step Toward FDA Submission for Stroke Reduction Device for Patients with Atrial Fibrillation

NATICK, Mass., July 2, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has completed enrollment in the PREVAIL confirmatory study, designed to gain U.S. Food and Drug Administration (FDA) approval for the WATCHMAN® Left Atrial Appendage (LAA) Closure device. The prospective, randomized trial enrolled 407 patients at 42 sites and is comparing the WATCHMAN device to warfarin in high-risk patients with atrial fibrillation (AF) eligible for long-term warfarin therapy. Patient follow up of six months is required prior to submission to the FDA.

"WATCHMAN is the most clinically studied device of its kind," said Vivek Reddy, M.D., Director of Cardiac Arrhythmia Service at Mount Sinai Medical Center and principal investigator of the PREVAIL study. "WATCHMAN has the potential to provide atrial fibrillation patients with a safe and effective first-in-class device-based solution to reduce risk of stroke."

The PREVAIL study began enrollment in November 2010. Patients were randomly selected to receive either the WATCHMAN device or remain on long-term warfarin therapy. Those selected to receive the WATCHMAN device remained on warfarin for 45 days following implant.

WATCHMAN has been studied in more than 2,000 patients, exceeding 4,000 patient-years of follow up. The evidence-based clinical program for WATCHMAN includes two landmark studies: the PROTECT AF trial and the ASA Plavix (ASAP) study. In the multi-center, randomized PROTECT AF trial, the WATCHMAN device proved to be 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 in 707 patients. Data from the prospective, multi-center ASAP study showed a 77 percent reduction of ischemic stroke risk in patients with AF implanted with the WATCHMAN device and not eligible for blood-thinning medications.

"WATCHMAN is already available in 30 countries. Enrollment completion of the PREVAIL study is a significant milestone in helping to bring this innovative therapy to patients living with atrial fibrillation in the U.S.," said Kenneth Stein, M.D., chief medical officer of Boston Scientific's Cardiac Rhythm Management Group. "We look forward to the results of PREVAIL and the opportunity to enter the structural heart space in the U.S."

WATCHMAN is a novel device manufactured by Boston Scientific Corporation that is introduced into the heart via a flexible tube (catheter) through a vein in the groin and closes 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.

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 are at a greater risk for 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.

The WATCHMAN device was approved for marketing in Europe and some countries in Asia in 2005. It is contraindicated in patients who are not eligible for anticoagulation therapy.

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 www.Atritech.net for more information.

About Boston Scientific
Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

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 markets for our products, regulatory approvals, business plans in the U.S. structural heart space, clinical trials, 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; 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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