

## **Boston Scientific's WATCHMAN® Device Implanted in First Patients in Latin America**

NATICK, Mass., Nov. 16, 2011 [PRNewswire/](#) -- Boston Scientific Corporation's (NYSE: BSX) WATCHMAN® Left Atrial Appendage (LAA) Closure Device has been implanted in the first patients in Latin America. The novel device is designed for use in patients in atrial fibrillation who are at risk for stroke and are eligible for long-term oral anticoagulation therapy such as warfarin. The WATCHMAN LAA Closure Device is intended to prevent embolization of thrombi that may form in the LAA, thereby preventing the occurrence of ischemic stroke and systemic thromboembolism in patients with non-valvular atrial fibrillation. The first patient implants were performed by Bernardo Caicedo, M.D., Interventional Cardiologist, at Angiografía de Occidente in Cali, Colombia.

Atrial fibrillation, which affects approximately 15 million patients worldwide, is a disorder that disrupts the heart's ability to beat regularly and pump blood efficiently. Patients in atrial fibrillation are at greater risk for stroke due to the formation and migration of clots in the left atrial appendage. Anticoagulants such as warfarin have traditionally been the only therapy for reducing stroke risk in these patients. Boston Scientific's WATCHMAN device is intended to be an alternative to long-term anticoagulation. It is designed to close the LAA, thereby preventing clots within the appendage from being dislodged into the bloodstream.

"I am excited to be part of the first patient implants of the WATCHMAN device in Latin America," said Dr. Caicedo. "The percutaneously delivered device promises to offer a safe and effective alternative for atrial fibrillation patients who cannot take long-term oral anticoagulants and have limited options to reduce their stroke risk. It incorporates a pre-loaded device that is both repositionable and retrievable to enhance its ease of use."

The WATCHMAN Device is the most clinically studied product of its kind currently available. In the multi-center, randomized PROTECT AF clinical trial, it proved to be non-inferior to warfarin and demonstrated a 38 percent relative risk reduction for a combined measure of stroke, cardiovascular death and systemic embolism compared to long-term warfarin therapy in 800 patients. The study also showed a 29 percent relative risk reduction in all stroke and a 90 percent relative risk reduction in hemorrhagic stroke compared to warfarin. Nearly 1,800 patients have now been recruited in WATCHMAN clinical trials with more than 2,700 patient-years of follow-up. The WATCHMAN device is CE Marked and was commercialized outside the United States in 2009.

"The WATCHMAN device has been well received in many CE Mark countries and we look forward to beginning commercial launch in select Latin American markets this quarter," said Hank Kucheman, Chief Executive Officer for Boston Scientific. "We are pleased to bring this technology to more customers and their patients worldwide."

Boston Scientific is currently enrolling U.S. patients in the PREVAIL study, a confirmatory study designed to gain Food and Drug Administration approval. Enrollment is expected to be completed in the first quarter of 2012. 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.

### **About Boston Scientific**

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: [www.bostonscientific.com](http://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 new product launches and launch cadence, regulatory approvals, clinical trials, markets for our products, product performance and acceptance 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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