

Favorable Clinical Study Results Reported With Dual Anti-Platelet Therapy After LAA Closure With WATCHMAN® Device

NATICK, Mass. and Paris, May 18, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced results from a clinical study evaluating the use of its WATCHMAN® Left Atrial Appendage Closure Device in patients with atrial fibrillation who have a contraindication to oral anticoagulants such as warfarin. Data were presented at the annual EuroPCR Scientific Program in Paris by Martin Bergmann, M.D., Department of Cardiology at the Asklepios Klinik St. Georg in Hamburg, Germany, and Principal Investigator of the study.

Atrial fibrillation (AF) is a disorder that affects the ability of the heart to beat regularly and pump blood efficiently. Patients with atrial fibrillation are at a greater risk for stroke due to the formation and dislodgment of clots in the left atrial appendage (LAA) of the heart. Anticoagulants such as warfarin have traditionally been the only therapy for reducing stroke risk in these patients. The WATCHMAN device is designed to exclude the left atrial appendage from the circulation, which is the source of most of the clots that cause stroke. For patients experiencing atrial fibrillation who are at high risk for stroke, the device offers an alternative to anticoagulant drugs, which are associated with an increased risk of bleeding.

"Patients with atrial fibrillation who cannot take oral anticoagulants have limited options to reduce their stroke risk," said Dr. Bergmann. "Early study results are promising of the WATCHMAN device as an alternative for stroke prevention in this high-risk patient population with patients using dual anti-platelet therapy in place of warfarin after LAA closure."

In the study, 24 patients with contraindications to warfarin were successfully implanted with the WATCHMAN device at a single center in Germany. Following the procedure, they received dual anti-platelet therapy for at least three months. Results showed that after a mean follow-up of 4.2 months, no cerebrovascular events or device dislodgements occurred. In a single case, a thrombus was observed and resolved after two weeks of treatment with heparin.

These results are consistent with clinical data from the multi-center ASA Plavix (ASAP) Registry recently presented at the 2011 American College of Cardiology by Dr. Vivek Reddy of Mount Sinai Medical Center in New York. This study evaluated 113 patients with contraindications to warfarin implanted with the WATCHMAN device and treated with dual anti-platelet therapy for six months post-procedure.

"The WATCHMAN LAA closure device is the only such product proven to be an effective alternative to life-long warfarin therapy in patients with atrial fibrillation," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "These study results show that post-procedural dual anti-platelet drug therapy may be an option for those high-risk patients implanted with the device who are unable to take warfarin. Our continued investment in clinical programs is designed to help physicians make informed, evidence-based decisions on how to best treat their patients."

In the multi-center, randomized PROTECT AF trial, the WATCHMAN device demonstrated a 38 percent relative risk reduction for stroke, cardiovascular death and systemic embolism compared to long-term warfarin therapy in 800 patients. The Company is currently enrolling patients in the PREVAIL study, a confirmatory study designed to gain U.S. Food and Drug Administration approval.

The CE Marked WATCHMAN device was commercialized outside the United States in 2009. In the U.S., it is an investigational device, limited by applicable law to investigational use and not available for sale. The device was developed by Atritech, which was acquired by Boston Scientific in March, for left atrial appendage closure in patients with atrial fibrillation.

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.

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 studies and 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.

CONTACT: Erik Kopp

508-650-8660 (office)

Media Relations

Boston Scientific Corporation

erik.kopp@bsci.com

Sean Wirtjes

508-652-5305 (office)

Investor Relations

Boston Scientific Corporation

investor_relations@bsci.com

SOURCE Boston Scientific Corporation

<https://news.bostonscientific.com/favorable-results-watchman-device-europcr-2011>