

The Boston Scientific PROMUS Element™ Platinum Chromium Stent Demonstrates Continued Low Event Rates Through Three Years

NATICK, Mass., March 10, 2013 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) reported clinical endpoint data from the PLATINUM workhorse clinical trial comparing the safety and effectiveness of the PROMUS Element™ Everolimus-Eluting Platinum Chromium (PtCr) Coronary Stent System to the Cobalt Chromium (CoCr) Xience V® Everolimus-Eluting Coronary Stent System. At three years, the PROMUS Element Stent continued to demonstrate advantages over the Xience V Stent. Data were presented today by Ian Meredith, M.D., Monash University, Melbourne, Australia, at the 62nd Annual Scientific Session of the American College of Cardiology in San Francisco.

Around the world, approximately four million people with cardiovascular disease are treated each year with stents used to help keep vessels open. Stents, which are placed and expanded to fit the size, shape and bend of the artery, may also be coated with a drug. Boston Scientific is continuously studying product performance in an effort to offer innovations that provide a positive impact on patient care and lower the costs of healthcare.

"The PROMUS Element Platinum Chromium Stent continues to demonstrate excellent safety and effectiveness with low rates of cardiac death, myocardial infarction, stent thrombosis and repeat revascularization," said Prof. Meredith. "These three-year results confirm that this device benefits patients with symptomatic coronary artery disease requiring Percutaneous Coronary Intervention."

The trial reported a three-year target lesion revascularization (TLR) rate of 3.5 percent for the PROMUS Element Stent, the lowest TLR rate in any pivotal FDA approval trial, compared to 4.9 percent for the Xience V Stent ($p=0.21$). Both the PROMUS Element and Xience V Stents demonstrated low rates of ARC/Definite stent thrombosis of 0.7 percent and 0.5 percent respectively ($p=0.76$). Trial results also confirmed a previously reported significant reduction in unplanned (bail-out or emergency) stenting with the PROMUS Element Stent compared to the Xience V Stent (5.9 percent vs. 9.8 percent, $p=0.004$), including a significantly lower rate of inadequate lesion coverage (1.4 percent vs. 3.4 percent, $p=0.01$). These clinical observations reinforce the results of comparative bench and pre-clinical studies, which have demonstrated the enhanced visibility and deliverability of the PROMUS Element Stent relative to the Xience V Stent. The reduction in bail-out stenting has also been tied to cost savings per procedure.

"With its outstanding deliverability, conformability and visibility, the PROMUS Element Stent offers interventional cardiologists an exceptional stenting option for patients with coronary artery disease," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "These data confirm consistent long term performance which supports our efforts to improve the lives of patients around the world."

Separately, Jeffrey Popma, M.D., Beth Israel Deaconess Medical Center, Boston, presented data that demonstrated significantly less vessel straightening, which may be associated with improved blood flow within the vessel, when using the conformable PROMUS Element Stent compared to the more rigid Xience V stent (40 percent relative reduction in angulation change from pre to post procedure with PROMUS Element, $P=0.01$).

"The PLATINUM three-year results support the theory that platform matters," said Popma. "The flexible and conformable platinum chromium PROMUS Element Stent causes less vessel straightening than Xience stents, possibly contributing to the low clinical event rates observed at three years with PROMUS Element Stents."

The PROMUS Element Stent, utilized in the PROMUS Element Stent System and the PROMUS Element™ Plus Stent System, uses a proprietary platinum chromium alloy designed specifically for coronary stenting, which enables enhanced visibility, less recoil, high fracture resistance, excellent conformability and higher radial strength. The PROMUS Element Plus Stent System features an advanced low-profile delivery system to facilitate precise delivery of the stent across challenging lesions.

Boston Scientific received CE Mark approval for the PROMUS Element Stent System in 2009 and for the PROMUS Element Plus Stent System in 2011. The PROMUS Element Plus Stent System was approved by the U.S. Food and Drug Administration in 2011.

Xience V is a trademark of the Abbott Laboratories group of companies.

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, clinical trials and impact of 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; 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:

Steven Campanini
508-652-5740 (office)
214-546-5034 (cell, March 7 - March 11)
Global Media Relations
Boston Scientific Corporation
media@bsci.com

Michael Campbell
508-650-8023 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

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