

PROMUS Element™ Stent Demonstrates Exceptional Safety and Effectiveness in PLATINUM Small Vessel Study

NATICK, Mass. and PARIS, May 20, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced 12-month results from its PLATINUM Small Vessel study, demonstrating excellent safety and effectiveness outcomes for the 2.25 mm [PROMUS Element™ Everolimus-Eluting Platinum Chromium Stent System](#) in treating small vessel coronary disease. The study is a global, prospective, single-arm, subtrial of the PLATINUM clinical program. It compares the PROMUS Element Stent (2.25 mm) in 94 patients with small vessels (greater than or equal to 2.25 to less than 2.50 mm reference vessel diameter and less than or equal to 28 mm lesion length) to a pre-specified performance goal based on results from patients treated with the TAXUS® Express® Paclitaxel-Eluting Stent.

Analysis of the data was presented at the annual EuroPCR Scientific Program in Paris by Ian T. Meredith, M.B.B.S., Ph.D., Professor of Cardiology and Medicine, Monash University, and Executive Director of Monash Cardiovascular Research Center, Monash Medical Centre, Clayton, Victoria, Australia, and Co-Principal Investigator for the PLATINUM clinical program.

"The PLATINUM Small Vessel data demonstrate exceptionally low rates of revascularization, while reporting no myocardial infarction or stent thrombosis at one year in patients treated with the 2.25 mm PROMUS Element Stent," said Professor Meredith. "These results are impressive, especially considering the small vessel diameter in this patient population."

The PLATINUM Small Vessel study met its primary endpoint of target lesion failure (TLF) at 12 months with a rate of 2.4 percent for the 2.25 mm PROMUS Element Stent in the per protocol population compared to a pre-specified performance goal of 21.1 percent ($p < 0.001$) based on historical outcomes for the 2.25 mm TAXUS Express Stent. Components of TLF in the per protocol population included cardiac death related to the target vessel (2.4 percent), myocardial infarction related to the target vessel (MI, 0.0 percent) and ischemia-driven target lesion revascularization (TLR, 0.0 percent). Clinical outcome rates at 12 months in the intent-to-treat population were also low for cardiac death (3.3 percent), MI (0.0 percent), TLR (2.2 percent) and ARC definite/probable stent thrombosis (0.0 percent).

"The PLATINUM Small Vessel data build on the positive outcomes from the PLATINUM Workhorse and QCA studies, confirming the successful transfer of favorable outcomes associated with everolimus to the novel platinum chromium (PtCr) stent design," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific's Cardiology, Rhythm and Vascular Group. "The results demonstrate a highly effective PtCr small vessel stent platform with an excellent safety profile."

"Boston Scientific has led development of drug-eluting stents for small vessels, which now represent approximately 10 percent of coronary stenting procedures," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "This evaluation of the 2.25 mm PROMUS Element Stent reconfirms our commitment to providing a complete range of solutions and sizes for physicians and their patients."

The PLATINUM clinical program is evaluating the safety and effectiveness of the PROMUS Element Stent in five multi-center studies totaling more than 1,800 patients, including a global, randomized, pivotal controlled trial in workhorse lesions, and single-arm studies evaluating small vessels, long lesions, pharmacokinetics, and quantitative coronary angiography and intravascular ultrasound data.

The PROMUS Element Stent System received CE Mark approval and was launched in Europe and other international markets in 2009. It features an innovative PtCr alloy and new stent design to offer greater radial strength, exceptional deliverability and high visibility. The thin-strut stent is designed for improved conformability, minimal recoil and uniform lesion coverage and drug distribution. The advanced low-profile delivery system, coupled with the radiopacity, facilitates precise delivery of the stent across challenging lesions.

The Company anticipates FDA approval for the PROMUS Element Stent, including the 2.25 mm PROMUS Element Stent, in mid 2012. In the U.S., it is an investigational device, limited by applicable law to investigational use and not available for sale.

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 trials, product performance, our business plans 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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