

PROMUS Element™ Stent Demonstrates Excellent Long-Term Safety and Effectiveness in PLATINUM Small Vessel Study

NATICK, Mass., May 18, 2012 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) announces two-year results from the PLATINUM Small Vessel study, demonstrating excellent safety and effectiveness outcomes for the 2.25 mm PROMUS Element™ Everolimus-Eluting Platinum Chromium (PtCr) Stent System in treating *de novo* coronary lesions in small coronary vessels. Analysis of the data was presented today at the annual EuroPCR Scientific Program in Paris.

"The PLATINUM Small Vessel data continue to demonstrate very low revascularization rates, with no myocardial infarction or stent thrombosis through two years of follow up in patients treated with the 2.25 mm PROMUS Element Stent," said Ian Meredith, Professor and Director of MonashHeart, at Monash Medical Centre in Melbourne, Australia, and co-principal investigator for the PLATINUM clinical program. "These long-term results are impressive, especially considering the small vessel diameters that were evaluated in this study."

The PLATINUM Small Vessel study previously 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 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® Paclitaxel-Eluting Stent. The TLF rate at two years was 4.7 percent with the 2.25 mm PROMUS Element Stent while the rate of target lesion revascularization (TLR) was 2.5 percent. Rates of other major adverse events remained low in patients treated with study stents at two years, including cardiac death (2.3 percent), myocardial infarction (0.0 percent) and Academic Research Consortium (ARC) definite/probable stent thrombosis (0.0 percent). There were no deaths between 1 and 2 years for patients treated with the 2.25 mm PROMUS Element Stent.

"The PLATINUM Small Vessel data build on the positive long-term outcomes from the PLATINUM Workhorse trial, which reported excellent safety and effectiveness of the PROMUS Element Stent in workhorse lesions and demonstrated superior efficacy compared to the XIENCE V® (PROMUS®) Stent in a landmark analysis of revascularization outcomes from year one to year two," said Keith D. Dawkins, M.D., global chief medical officer for Boston Scientific. "The results demonstrate a highly effective platinum chromium small vessel stent platform with an excellent safety profile. This study of the 2.25 mm PROMUS Element Stent reconfirms our commitment to providing a complete range of stenting solutions and sizes for physicians and their patients."

Boston Scientific received CE Mark approval for the PROMUS Element Stent System in 2009 and for the PROMUS Element Plus Stent System in 2011. In the U.S., the PROMUS Element Plus Stent System was approved by the Food and Drug Administration in 2011. The PROMUS Element Stent, part of the PROMUS Element Stent System and the PROMUS Element Plus Stent System, employs a proprietary PtCr alloy designed specifically for coronary stenting, which enables enhanced visibility, less recoil, excellent conformability and higher radial strength. The PROMUS Element Plus Stent System employs an advanced low-profile delivery system, designed to facilitate precise delivery of the stent across challenging lesions.

XIENCE is a trademark of the Abbott Laboratories group of companies. PROMUS is a private-labeled XIENCE V everolimus-eluting stent system manufactured by Abbott and distributed by Boston Scientific.

About the PLATINUM Small Vessel Study

The PLATINUM Small Vessel study is a prospective, multicenter, single-arm, subtrial of the PLATINUM clinical program designed to evaluate the safety and effectiveness of the PROMUS Element Stent (2.25 mm) for the treatment of *de novo* coronary lesions in patients with small vessels (greater than or equal to 2.25 to <2.50 mm reference vessel diameter and less than or equal to 28 mm lesion length).

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 our business plans, regulatory approvals, clinical trials and clinical outcomes, 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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