Boston Scientific

Boston Scientific's PROMUS Element™ Platinum Chromium Stent Demonstrates Excellent Outcomes in Patients With Long Coronary Lesions

NATICK, Mass. and SAN FRANCISCO, Nov. 8, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) reports clinical endpoint data from its PLATINUM Long Lesion trial, demonstrating excellent outcomes for the PROMUS Element™ Everolimus-Eluting Platinum Chromium (PtCr) Stent System in patients with long coronary lesions. Results were presented today by Paul S. Teirstein, M.D., of the Scripps Clinic in La Jolla, California, and Co-Principal Investigator of the trial, at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Francisco.

The PLATINUM Long Lesion trial compared the PROMUS Element Stent System in patients with long *de novo* lesions (>24 to less than or equal to 34 mm in length and greater than or equal to 2.50 to less than or equal to 4.25 mm in diameter) to a pre-defined performance goal based on historical results in patients treated with the 32 mm TAXUS® Express2™ Paclitaxel-Eluting Stent System. The prospective, single-arm trial enrolled 102 patients at 30 sites.

"The PROMUS Element Stent achieved impressive clinical outcomes in this patient population with long lesions," said Dr. Teirstein. "This everolimus-based stent, built on an advanced platinum chromium platform, demonstrated low rates of revascularization while reporting no cardiac death, myocardial infarction or stent thrombosis at one year, and should offer physicians greater confidence and flexibility in treating longer lesions with a single stent."

The PLATINUM Long Lesion study met its primary endpoint of target lesion failure (TLF) at 12 months with a 3.2 percent rate for the PROMUS Element Stent in the per protocol population compared to a pre-specified performance goal of 19.4 percent ($p<0.001$) based on historical outcomes for the TAXUS Express Stent. Components of TLF in the per protocol population for the PROMUS Element Stent included cardiac death related to the target vessel (0.0 percent), myocardial infarction (MI or heart attack) related to the target vessel (0.0 percent) and ischemia-driven target lesion revascularization (TLR, 3.2 percent). Clinical outcome rates at 12 months in the intent-to-treat population were low for all death (1.0 percent), cardiac death (0.0 percent), MI (0.0 percent), TLR (3.1 percent) and ARC definite/probable stent thrombosis (0.0 percent). Clinical procedural success was achieved in 100 percent of patients.

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

The PROMUS Element Stent System received CE Mark approval and was launched in Europe and other international markets in 2009. In February 2011, Boston Scientific launched the PROMUS Element Stent System in India, and, in October, announced the commencement of a phased launch in China. The PROMUS Element Stent 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 increased radiopacity, facilitates precise delivery of the stent across challenging lesions.

In the U.S., the PROMUS Element Stent is an investigational device, limited by Federal law to investigational use only 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 FDA approval and U.S. launch of the PROMUS Element Stent, clinical trials and product performance. 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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