Boston Scientific

Boston Scientific Announces Clinical Data Supporting Safety and Efficacy of Platinum Chromium PROMUS Element™ Stent

Nine-month results from PLATINUM clinical program presented at TCT

NATICK, Mass., Sept. 21 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced data from its PLATINUM QCA study, which is designed to evaluate the Company's PROMUS Element™ Everolimus-Eluting Platinum Chromium Coronary Stent. The results provided 30-day and nine-month clinical outcomes and nine-month quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS) data supporting the safety and efficacy of the PROMUS Element Stent. Analysis of the data was presented by Ian Meredith, M.B.B.S., Ph.D., Director of Cardiology at the Monash Medical Centre in Melbourne, Australia and Principal Investigator of the PLATINUM QCA study, at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics scientific symposium in Washington, D.C.

The PROMUS Element Stent features a novel platinum chromium (PtCr) alloy and innovative stent design, which combine to offer greater radial strength and flexibility while reducing stent recoil. The stent geometry helps create consistent lesion coverage and drug distribution while improving deliverability, which is enhanced by an advanced catheter delivery system. The higher density PtCr alloy provides superior visibility while permitting thinner struts compared to prior-generation stents (1).

"The nine-month angiographic and IVUS data from the PLATINUM QCA study are impressive and show the acute performance advantages of the platinum chromium PROMUS Element Stent," said Prof. Meredith. "With the same drug and polymer loading and comparable release kinetics as the PROMUS® Stent, the PROMUS Element Stent achieved similar late loss and significantly better stent apposition. These results give me great confidence in the transferability of the everolimus drug and its proven clinical outcomes, as well as the potential benefits of the new platinum chromium alloy."

The PLATINUM clinical program is evaluating the safety and efficacy of the PROMUS Element Stent in five multi-center studies totaling more than 1,800 patients, including a randomized controlled trial for workhorse lesions, as well as single-arm studies evaluating small vessels, long lesions and pharmacokinetics. The prospective, single-arm PLATINUM QCA study enrolled 100 patients at 14 sites.

The PLATINUM QCA primary endpoint of 30-day composite cardiac events was 1.0 percent, which included cardiac death (0.0 percent), myocardial infarction (0.0 percent), target lesion revascularization (TLR, 1.0 percent) and stent thrombosis (ARC (2) definite/probable, 1.0 percent). Of the 100 patients studied, one patient experienced a peri-procedural stent thrombosis and TLR. No additional major clinical events were reported from 31 days to nine months.

The study also met its pre-specified efficacy endpoint of in-stent late loss in workhorse lesions at nine months as measured by QCA compared to historical TAXUS® Express® Stent data. The PROMUS Element nine-month in-stent late loss of 0.17 mm +/- 0.25 mm was superior to the performance goal of 0.44 mm ($p<0.001$) based on TAXUS Express historical data and similar to in-stent late loss reported for the PROMUS (Xience V®) Everolimus-Eluting Stent in the SPIRIT trials.

The study met a second pre-specified efficacy endpoint of post-procedure incomplete stent apposition as measured by IVUS compared to PROMUS (Xience V) data from the SPIRIT III trial. The PROMUS Element post-procedure incomplete stent apposition of 5.7 percent was significantly below the performance goal of 34.4 percent ($p<0.001$) based on PROMUS (Xience V) historical data. The percent net volume obstruction at nine months as measured by IVUS was also low at 7.2 percent.

"These results demonstrate the successful transfer of drug and polymer from the PROMUS Stent to the PROMUS Element Stent," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific's Cardiology, Rhythm and Vascular Group. "The PLATINUM QCA results further support the performance of the everolimus drug/polymer combination while demonstrating a highly effective platinum chromium PROMUS Element Stent platform. The PROMUS Element Stent also demonstrates an excellent safety profile in this study with only a single patient experiencing a cardiac event within 30 days and no additional events through nine months."

"We are extremely pleased with the positive safety and efficacy results of the PLATINUM QCA study, which reinforce the overall benefits provided by our new platinum chromium stent platform," said Hank Kucheman, Executive Vice President and President of Boston Scientific's Cardiology, Rhythm and Vascular Group. "These favorable outcomes for our everolimus-eluting PROMUS Element Stent, together with the recent European launch of our paclitaxel-eluting TAXUS® Element™ Stent, illustrate our unparalleled pipeline of drug-eluting stent technologies."

The Company expects U.S. Food and Drug Administration approval for the TAXUS Element Stent System (3) in mid 2011 and for the PROMUS Element Stent System in mid 2012. In Japan, the Company expects approval for the TAXUS Element Stent System in late 2011 or early 2012 and for the PROMUS Element Stent System in mid 2012.

The randomized, controlled PLATINUM Workhorse clinical trial completed enrollment in September 2009 with 1,531 patients at more than 130 sites worldwide and compares the PROMUS Element Everolimus-Eluting Coronary Stent System to the PROMUS (Xience V) Everolimus-Eluting Coronary Stent System. One-year data from the trial will be presented at the Scientific Session of the American College of Cardiology/i2 Summit in March 2011.

In the U.S., the PROMUS Element and TAXUS Element systems are investigational devices and are limited by applicable law to investigational use only and are not available for sale.

The PROMUS Stent is a private-labeled Xience V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. The SPIRIT Clinical Program is sponsored by Abbott.

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 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.

(1) Based on bench testing. Data on file with Boston Scientific.

(2) Academic Research Consortium

(3) The TAXUS Element Stent System will be commercialized as the ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System in the U.S.

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