Boston Scientific

Boston Scientific Receives FDA Approval for PROMUS Element™ Plus Platinum Chromium Stent System

Approval marks transition to internally manufactured everolimus-eluting stent in the U.S.

NATICK, Mass., Nov. 22, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces U.S. Food and Drug Administration (FDA) approval for the PROMUS Element™ Plus Everolimus-Eluting Platinum Chromium Coronary Stent System, the Company's next-generation drug-eluting stent (DES) technology. The PROMUS Element Stent, designed to provide physicians improved DES performance in treating patients with coronary artery disease, is built on an innovative platinum chromium (PtCr) platform with the market-leading everolimus drug. The Company plans to begin marketing the product in the U.S. immediately.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/43510-boston-scientific-fda-promus-element-plus-platinum-chromium-stent-system

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The PROMUS Element Stent uses a proprietary PtCr alloy designed specifically for coronary stenting, which enables thinner struts and enhanced visibility. The innovative design offers a more conformable stent with less recoil and higher radial strength. It employs an advanced low-profile delivery system featuring a dual-layer balloon and Bi-Segment™ inner lumen catheter designed to facilitate precise stent delivery across challenging lesions. The everolimus drug and fluorinated copolymer stent coating have been studied in multiple randomized clinical trials and 'real-world' registries, demonstrating excellent long-term safety and efficacy.

"This approval marks an important milestone for Boston Scientific -- the beginning of a transition to higher margins on our everolimus stent offering in the U.S. as we shift from the PROMUS Stent to the internally manufactured PROMUS Element Plus Stent System," said Hank Kucheman, Chief Executive Officer of Boston Scientific. "In these challenging markets, this opportunity should represent $200M in additional annualized gross margin contribution for the U.S. and Japan exiting 2012, which is part of the $650M to $750M opportunity for improvements in operating profit expected over the next several years. The PROMUS Element Plus Stent System is also the latest example of our unparalleled pipeline of drug-eluting stent technologies and reflects our commitment to global DES market leadership. We are proud that our research, clinical, regulatory and manufacturing teams delivered a self-manufactured everolimus stent several months ahead of our goal."

The Company expects to record a pre-tax charge of approximately $40 million ($35 million after-tax) during the fourth quarter of 2011 as a result of the early approval and launch timing of the PROMUS Element Plus Stent System in the U.S. primarily related to inventory reserves which will impact gross margins. This charge was not included in the Company's previously issued financial guidance for the fourth quarter.

PLATINUM Clinical Program

The PROMUS Element Stent is supported by the comprehensive PLATINUM clinical program, which included five multi-center studies totaling more than 1,800 patients worldwide. In September 2010, data were presented on 30-day and nine-month clinical outcomes and nine-month angiographic and IVUS outcomes supporting the safety and effectiveness of the PROMUS Element Stent while demonstrating an acute procedural benefit with low rates of incomplete stent apposition. In April 2011, 12-month results announced from the randomized, controlled PLATINUM Workhorse trial demonstrated the clinical non-inferiority of the PROMUS Element Stent in comparison to the PROMUS Stent in treating *de novo* coronary artery lesions while also showing a procedural benefit of reduced rates of geographic miss and unplanned (bail-out or emergency) stenting.

"The clinical results we observed with the PROMUS Element Stent compared to the PROMUS Stent in the large-scale PLATINUM Workhorse trial, including extremely low rates of stent thrombosis, demonstrate that excellent clinical outcomes are achieved with this novel coronary stent system," said Gregg W. Stone, M.D., Professor of Medicine and the Director of Research and Education at the Center for Interventional Vascular Therapy at Columbia University Medical Center/New York-Presbyterian Hospital and Principal Investigator of the PLATINUM Workhorse trial.

Additional 12-month results from two single-arm subtrials support PROMUS Element Stent safety and effectiveness in small vessels and long lesions. The PLATINUM Small Vessel study demonstrated excellent safety and effectiveness outcomes, including no stent thrombosis or myocardial infarction for the 2.25 mm PROMUS Element Stent in treating small vessel coronary disease. The PLATINUM Long Lesion trial demonstrated low rates of revascularization while reporting no cardiac death, myocardial infarction or stent thrombosis at one year in patients with long coronary lesions.

"The extensive body of positive clinical evidence from the PLATINUM program demonstrates the successful transfer of safety and effectiveness of the leading everolimus stent to the novel PtCr platform, while supporting the acute performance benefits observed in real-world practice," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific's Cardiology, Rhythm and Vascular Group. "We are the only company to offer physicians a choice of two proven drug and polymer combinations on an advanced coronary stent platform. With the continued success of our Element platform in international markets and the ION™ Paclitaxel-Eluting Stent System in the U.S., we are confident the PROMUS Element Plus Stent System will be well received upon launch."

The PROMUS Element Plus Stent System is currently offered in a matrix of 74 sizes, ranging in diameter from 2.25 mm to 4.00 mm and lengths of 8 mm to 32 mm on both Monorail® and Over-the-Wire catheter platforms. The Company expects that additional 32 mm and 38 mm stent lengths will be available in mid-2012. Boston Scientific has the industry's most comprehensive coronary stent portfolio, offering physicians and their patients a broad size matrix and the only two-drug platform.

The Company received CE Mark approvals for the PROMUS Element Everolimus-Eluting Stent System in October 2009, the TAXUS® Element Paclitaxel-Eluting Stent System in May 2010, and the OMEGA™ Bare-Metal Coronary Stent System in February 2011. We expect to receive regulatory approval of the PROMUS Element Stent System and launch the product by mid-2012 in Japan. In the U.S. the TAXUS Element Stent is commercialized as the ION Paclitaxel-Eluting Stent, which received FDA approval in April 2011. All systems incorporate the same PtCr alloy and innovative stent design. The PROMUS Element Plus Stent System combines the PROMUS Element Stent with an enhanced catheter delivery system engineered for improved deliverability in challenging coronary lesions. In the U.S., the OMEGA Bare-Metal Coronary Stent System is an investigational device and is 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 "should," "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words.

These forward-looking statements include, among other things, statements regarding our business plans, opportunities for operating profit improvement, future gross margin contributions, charges related to inventory reserves, product pipeline, 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; regulatory approvals; new product introductions, launches and launch cadence; market conditions and acceptance of our products; performance and perceived performance of our products; clinical trials; 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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