Boston Scientific

Boston Scientific Receives FDA Approval for 32 MM and 38 MM Lengths for PROMUS Element™ Plus Platinum Chromium Stent System

PROMUS Element Plus Stent System Offers Physicians the Broadest Array of Everolimus Drug-eluting Stent lengths and diameters in the U.S.

NATICK, Mass., June 4, 2012 /PRNewswire/ -- The U.S. Food and Drug Administration (FDA) has provided Boston Scientific Corporation (NYSE: BSX) regulatory approval of 32 mm and 38 mm lengths 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 is built on an innovative platinum chromium (PtCr) platform with the market-leading everolimus drug and is designed to provide physicians exceptional DES performance in treating patients with coronary artery disease. The 32 and 38 mm lengths of the PROMUS Element Plus Stent System are immediately available in the U.S.

The PROMUS Element Plus Stent System is now available in a matrix of 94 sizes, ranging in diameter from 2.25 mm to 4.00 mm and lengths of 8 mm to 38 mm on both Monorail® and Over-the-Wire catheter platforms. Boston Scientific has the industry's most comprehensive coronary stent portfolio, and is the only company to offer physicians a choice of two proven drugs on an advanced coronary stent platform. In addition to the PROMUS Element Plus Stent System, Boston Scientific offers the OMEGA™ Bare-Metal Stent System and TAXUS® Element™ Paclitaxel-Eluting Stent System in international markets and the ION™ Paclitaxel-Eluting Stent System in the U.S.

Clinical data support the safety and efficacy of the PROMUS Element Stent in patients with long coronary lesions. As part of the comprehensive PLATINUM Clinical Trial program, the one year data from the PLATINUM Long Lesion Trial demonstrated low rates of revascularization while reporting no cardiac death, myocardial infarction or stent thrombosis in patients with long coronary lesions. The PLATINUM Long Lesion Trial is a prospective, multicenter, single-arm subtrial designed to evaluate the safety and effectiveness of the PROMUS Element Stent for the treatment of *de novo* coronary lesions >24 mm to less than or equal to 34 mm in length (greater than or equal to 2.50 to less than or equal to 4.25 mm in diameter).

"The extensive evidence base from the PLATINUM trials documents the excellent safety and efficacy of the PROMUS Element Plus Stent System, including extremely low rates of stent thrombosis," said Louis Cannon, M.D., FACC, FSCAI, FACP, program director at the Heart and Vascular Institute of the Northern Michigan Hospital, who has used the 32 mm and 38 mm length stents as part of the PLATINUM Clinical Trial Program. "The impressive patient outcomes achieved with the PROMUS Element Plus Stent System in clinical study and in day-to-day practice are especially relevant when treating patients with long lesions, which are often challenging cases representing complex disease. What's more, we're achieving these results with a highly deliverable stent system that features stents of unparalleled radial strength, conformability and visibility."

"This latest regulatory approval addressing the long sizes of the PROMUS Element Plus Stent System marks yet another important milestone for Boston Scientific — we now offer the market-leading everolimus drug on our PtCr stent platform in the broadest range of lengths and diameters in the United States," said Kevin Ballinger, president of Boston Scientific's cardiovascular division. "We continue to secure regulatory approvals and introduce the breakthrough PROMUS Element Plus Stent System, now available in the United States and the European Union. Notably, this is an internally developed and manufactured drug-eluting stent system, underscoring Boston Scientific's commitment to global DES market leadership."

The company received CE Mark approval for the PROMUS Element Stent System in 2009. The PROMUS Element Plus Stent System was approved by the FDA and received CE Mark in 2011. The TAXUS® Element™ Paclitaxel-Eluting Stent System received CE Mark approval in 2010 and approval in Japan in 2011. It received FDA approval in 2011 and is marketed in the U.S. as the ION™ Paclitaxel-Eluting Stent System.

About the PROMUS Element Plus Coronary Stent System

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.

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, the global DES market and our market position, 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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