

Boston Scientific Launches Promus Element™ Stent System In China

NATICK, Mass., Oct. 17, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) has begun a phased launch of its PROMUS Element™ Everolimus-Eluting Platinum Chromium Coronary Stent System in China. The launch campaign will be expanded within the country based upon receipt of subsequent provincial reimbursement approvals. The Company previously received registration approval for the PROMUS Element™ Stent System from the State Food and Drug Administration (SFDA) of the People's Republic of China.

The product represents the Company's third-generation drug-eluting stent (DES) technology, which incorporates a novel platinum chromium (PtCr) alloy, innovative stent design and advanced catheter delivery system. It offers greater strength, enhanced deliverability and exceptional visibility, and is designed for improved conformability, minimal recoil, and uniform lesion coverage and drug distribution. The advanced low-profile delivery system facilitates precise delivery of the stent across challenging lesions.

"The PROMUS Element Stent represents a true next-generation DES technology and its unique platinum chromium alloy addresses many of the limitations found in older stent alloys," said Runlin Gao, M.D., of the Cardiovascular Institute and Fu Wai Hospital in Beijing, and Principal Investigator of the PLATINUM China trial. "In my clinical experience, I have found it to offer performance advantages in flexibility, visibility and deliverability. It will be an important additional treatment option for the growing incidence of coronary artery disease in China."

With the world's largest population, China represents one of the world's fastest-growing DES markets. The Company estimates the number of coronary drug-eluting stents implanted there in 2011 will be approximately 560,000, with annual market growth exceeding 20 percent, making it the second-largest DES market worldwide after the United States.

"The Chinese government has announced its intention to spend \$125 billion on its healthcare system in the next five years, and the launch of our advanced coronary stenting technology in China reflects our intention to tap into its expanding, promising DES market," said Larry Neumann, Senior Vice President and President, Emerging Markets at Boston Scientific. "We are making significant investments in our sales, distribution and clinical infrastructure in China and this important launch reflects our goal to win global market share as part of our 'POWER' strategic plan."

In July, the Company's Board of Directors approved a five-year, \$150 million investment in China to establish a local, wholly owned manufacturing facility focused on serving Chinese market needs and developing a world-class training center for Chinese healthcare providers. As a result of this increased investment, as well as current and anticipated initiatives, Boston Scientific indicated in July that it expects to increase its revenues in China to more than \$500 million exiting 2016. The Company also estimated that its target market in China currently exceeds \$1 billion and is growing approximately 20 percent annually.

PLATINUM clinical program

The PLATINUM China post-SFDA approval clinical trial is comparing the PROMUS Element Stent to the TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent in the treatment of patients with a single *de novo* atherosclerotic lesion. It is a prospective, randomized trial that will enroll 500 patients at 15 sites in China.

In addition, the PROMUS Element Stent is being evaluated in a separate PLATINUM clinical program, which includes five multi-center studies totaling more than 1,800 patients worldwide. Thirty-day and nine-month clinical and angiographic outcomes presented in September 2010 supported the safety and efficacy of the PROMUS Element Stent. In April 2011, 12-month results announced from the PLATINUM Workhorse randomized, controlled 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 unplanned (bail-out or emergency) stenting.

"Positive clinical data from our PLATINUM trials demonstrate the successful transfer of safety and efficacy of the leading everolimus-eluting stent to the PtCr Element 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. "As a result, the PROMUS Element Stent has been well received in every country where it has been introduced."

In the U.S., the PROMUS Element Stent is an investigational device, limited by applicable law to investigational use 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 our strategic plans and investments, new product launches and launch cadence, regulatory and provincial approvals in China, investments by the Chinese government, clinical trials, markets for our products and our market share of those markets in China, future revenues in China, product performance and acceptance, 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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