Boston Scientific Begins Clinical Trial Enrollment in China for PROMUS Elementâ„¢ Everolimus-Eluting Stent

Boston Scientific

NATICK, Mass., Jan. 26, 2011 /PRNewswire [1]/ -- Boston Scientific Corporation (NYSE: BSX) today announced the beginning of patient enrollment in the PLATINUM China clinical trial, which is designed to evaluate the safety and effectiveness of the Company's PROMUS Element™ Everolimus-Eluting Platinum Chromium Coronary Stent compared to the TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent in the treatment of patients with a single *de novo* atherosclerotic lesion. PLATINUM China is a prospective, randomized trial that will enroll 500 patients at 15 sites in China. Clinical data from the trial will be used to support approval of the PROMUS Element Stent by the State Food and Drug Administration of the People's Republic of China.

The first patient was enrolled in the PLATINUM China trial this week at Shenyang Northern Hospital by Yaling Han, M.D., the Co-Principal Investigator of the trial. The Principal Investigator is Runlin Gao, M.D., of the Cardiovascular Institute and Fu Wai Hospital in Beijing.

"I am enthusiastic about the start of enrollment in the PLATINUM China trial and for the potential of this advanced stent platform as a treatment option for my patients with coronary artery disease," said Dr. Gao. "The new alloy and stent design of the PROMUS Element Stent promise to offer improved deliverability and visibility, even in patients with complex and challenging anatomy."

The PROMUS Element Stent features a novel platinum chromium 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 platinum chromium alloy provides superior visibility while permitting thinner struts compared to prior-generation stents(1).

"PLATINUM China represents the Company's first major coronary drug-eluting stent trial with enrollment exclusive to China," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer, Cardiology, Rhythm and Vascular Group for Boston Scientific. "The Element Stent series has been well received by physicians in CE Mark countries, and we look forward to bringing this advanced coronary stenting technology to Chinese physicians and their patients."

The Company received CE Mark approval for the PROMUS Element Everolimus-Eluting Stent System in October 2009 and for the TAXUS® Element™ Paclitaxel-Eluting Stent System in May 2010. Both Element systems incorporate the same platinum chromium alloy, innovative stent design and advanced catheter delivery

system.

"We are excited to begin evaluating the PROMUS Element Stent in China," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "The advanced platinum chromium alloy and new balloon catheter offered in the Element Stent System represent significant improvements over prior-generation stents. We are confident that the next-generation Element platform will further extend our global drug-eluting stent leadership."

In the U.S., the Company expects Food and Drug Administration approval for the TAXUS Element Stent System(2) 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.

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

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

(2) In the U.S., the TAXUS Element Stent System will be commercialized as the ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System.

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 [2].

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 clinical trials, regulatory approvals, competitive offerings, product performance and our market position. 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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