

Boston Scientific

Boston Scientific Completes Enrollment in Pivotal Workhorse Trial for Next-Generation Everolimus Stent

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NATICK, Mass., Sept. 18 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced the completion of patient enrollment in the workhorse portion of its PLATINUM clinical program. PLATINUM is a global, randomized, pivotal controlled trial designed to support U.S. Food and Drug Administration (FDA) and Japanese Ministry of Health, Labor and Welfare (MHLW) approval of the platinum chromium PROMUS(®) Element™ Everolimus-Eluting Coronary Stent System. The trial enrolled 1,532 patients with up to two de novo lesions at more than 140 sites worldwide, and completed enrollment two months ahead of schedule.

The PLATINUM workhorse trial evaluates the new PROMUS Element Everolimus-Eluting Coronary Stent in comparison with the current PROMUS Stent, which uses the same drug dose and polymer on an earlier cobalt chromium alloy stent design. Two parallel sub-trials will evaluate the PROMUS Element Stent in small vessels and long lesions. In addition to the PROMUS Element Everolimus-Eluting Stent, the Company is developing additional variations of a bare-metal and paclitaxel-eluting stent on the Element platform. The pivotal PERSEUS clinical trial compares the TAXUS(®) Element™ Stent to the TAXUS Express2™ Stent. The PERSEUS trial completed enrollment in October 2008, and the primary endpoint will be reported at the ACC conference in 2010.

"The brisk enrollment in the PLATINUM trial reflects the strong interest in this new platinum chromium stent platform," said Gregg W. Stone, M.D., Professor of Medicine and the Director of Research and Education at the Center for Interventional Vascular Therapy at the Columbia University Medical Center/New York-Presbyterian Hospital and Principal Investigator of the trial.

The Element Stent platform features a proprietary platinum chromium alloy, designed specifically for coronary stents. This alloy, coupled with a new stent architecture, is designed to allow thinner struts, increased flexibility and a lower profile, while improving radial strength, recoil and visibility. In addition, all three Element Stents incorporate the new Apex™ Dilatation Catheter technology, designed to enhance deliverability.

"We are pleased to bring the next-generation Element drug-eluting stent platform another step closer to commercialization," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular for Boston Scientific. "We are confident that the next-generation Element platform - to be offered in everolimus, paclitaxel and bare-metal versions - will further extend our global drug-eluting stent leadership."

The PROMUS Element, TAXUS Element and bare-metal Element Stents are investigational devices and are limited by applicable law to investigational use only and are not available for sale.

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 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 thereafter. 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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