

Boston Scientific

Boston Scientific Completes Clinical Trial Enrollment for Third-Generation Drug-Eluting Stent

PERSEUS clinical program to evaluate TAXUS® Element™ Platinum Chromium Stent

PRNewswire-FirstCall

NATICK, Mass.

(NYSE:BSX)

NATICK, Mass., Oct. 8 /[PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has completed enrollment in the PERSEUS trial, designed to evaluate the Company's third-generation TAXUS® Element™ paclitaxel-eluting coronary stent. The PERSEUS clinical program has enrolled nearly 1,500 patients at 100 U.S. and international centers since July 2007, and will compare the TAXUS Element Stent to the prior-generation TAXUS® Express2™ Stent marketed in the United States since 2004. The Company plans to develop additional versions of the Element platform, including next generations of a bare-metal stent and an everolimus-eluting PROMUS® Element stent system.

"We are pleased to reach this important milestone in the development of our third-generation drug-eluting stent, at a time when most companies are still introducing their first-generation stents in the U.S.," said Keith Dawkins, M.D., Senior Vice President and Associate Chief Medical Officer for Boston Scientific. "Boston Scientific is the only company to offer interventionalists a choice between two different drugs in a DES platform. The advanced Platinum Chromium Alloy and new balloon catheter offered in the Element system will further strengthen our deep portfolio of coronary stent technologies."

The Element Stent platform features the proprietary Platinum Chromium Alloy, designed specifically for stents. This alloy, coupled with an innovative new stent architecture, is designed to enable thinner struts for increased flexibility, a lower profile, and improved radial strength, recoil, and radiopacity. In addition, the TAXUS Element Stent System incorporates new balloon technology, intended to improve on Boston Scientific's market-leading Maverick® Balloon Catheter platform.

"The new alloy and stent design of TAXUS Element provides improved deliverability and visibility, even in patients with complex and challenging anatomy," said Dean J. Kereiakes, M.D., Medical Director at The Christ Hospital Heart and Vascular Center and The Lindner Research Center in Cincinnati and the principal investigator for the trials. "I am very enthusiastic about the potential the TAXUS Element Stent offers me to treat a broader range of patients."

The TAXUS PERSEUS clinical program will evaluate the efficacy and safety of the TAXUS Element Stent in two studies.

The first study, TAXUS PERSEUS Workhorse (A Prospective Evaluation in a Randomized Trial of the Safety and Efficacy of the Use of the TAXUS Element Paclitaxel-Eluting Coronary Stent System for the Treatment of De Novo Coronary Artery Lesions), will evaluate the safety and efficacy of the TAXUS Element Stent compared to Boston Scientific's first generation drug-eluting stent, the TAXUS® Express™ Stent. This 3:1 randomized study will evaluate 1,264 patients from 94 sites in the U.S., Australia, New Zealand and Singapore with "workhorse" lesions from 2.75 to 4.0 millimeters in diameter. The primary endpoint of the workhorse study is target lesion failure (TLF) at 12 months, and its secondary endpoint is in-segment percent diameter stenosis at nine months.

A second parallel study named the TAXUS PERSEUS Small Vessel study will compare the TAXUS Element Stent to a historic control (TAXUS V de novo bare-metal Express® Coronary Stent System). This study will include 224 patients from 35 U.S. sites with lesions from 2.25 up to 2.75 millimeters. The primary endpoint of the small vessel study is in-stent late loss at nine months, and its secondary endpoint is TLF at 12 months.

The TAXUS Element Stent is an investigational device and is limited by Federal law to investigational use only and is not available for sale. Boston Scientific is currently seeking CE Mark approval in European markets, which is anticipated in 2009.

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: <http://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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