Boston Scientific

# Boston Scientific Begins Clinical Trial Enrollment for New Everolimus-Eluting Stent

PRNewswire
NATICK, Mass.
(NYSE:BSX)

**PLATINUM clinical program to evaluate PROMUS™ Element™ Platinum Chromium Stent**

NATICK, Mass., Feb. 3 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today announced the beginning of patient enrollment in the PLATINUM clinical trial, which is designed to evaluate the Company's PROMUS™ Element™ Everolimus-Eluting Coronary Stent. The first U.S. patient was enrolled last week at the Medical Center of the Rockies in Loveland, Colorado by Thomas Downes, M.D. The first Japanese patient was also enrolled last week.

The PLATINUM clinical program will enroll 1,728 patients at 160 sites worldwide. The trial will compare the PROMUS Element Everolimus-Eluting Coronary Stent to the PROMUS™ Everolimus-Eluting Coronary Stent. The Company plans to develop additional variations of the Element Stent platform, including next generations of a bare-metal stent and a paclitaxel-eluting TAXUS® Element Stent.

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 enable thinner struts, increased flexibility and a lower profile while improving radial strength, recoil and visibility. In addition, the PROMUS Element Stent System incorporates the new Apex™ Dilatation Catheter technology, designed to enhance deliverability to complex lesions.

"We are excited to begin evaluating the everolimus version of our third-generation Element Stent," said Keith Dawkins, M.D., Senior Vice President and Associate Chief Medical Officer for Boston Scientific. "The advanced Platinum Chromium Alloy and new balloon catheter offered in the Element Stent System represent significant improvements. Boston Scientific is the only company to offer interventional cardiologists a choice of two different drugs on its drug-eluting stent (DES) platform."

The global Principal Investigator for the trial is Gregg W. Stone, M.D., of Columbia University Medical Center and the Cardiovascular Research Foundation in New York. The U.S. Co-Principal Investigator is Paul Teirstein, M.D., of Scripps Green Hospital in La Jolla, California, and the International Co-Principal Investigator is Ian Meredith, M.D., Ph.D., Director of Cardiology at the Monash Medical Centre in Melbourne, Australia.

"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," said Dr. Stone. "I am enthusiastic about the possibility of having both everolimus and paclitaxel versions of this innovative stent system available, allowing for the tailored treatment of patients with coronary artery disease."

"Patient enrollment in the PLATINUM trial is scheduled to be completed by October," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular for Boston Scientific. "This should enable U.S. and Japanese launches of an internally developed everolimus stent -- PROMUS Element -- consistent with the expiration of our existing PROMUS supply agreement in mid-2012. We plan to launch PROMUS Element in Europe during the fourth quarter of this year."

The PLATINUM clinical program will evaluate the safety and efficacy of the PROMUS Element Stent in three studies.

The first, PROMUS PLATINUM Workhorse, will evaluate the safety and efficacy of the PROMUS Element Stent compared to Boston Scientific's PROMUS Stent. This 1:1 randomized study will evaluate 1,532 patients from 160 global sites with de novo "workhorse" lesions from 2.50 to 4.25 mm in diameter and less than 24 mm in length. The primary endpoint of the workhorse study is target lesion failure (TLF) at 12 months, with clinical follow-up scheduled out to five years.

Two additional parallel studies will evaluate the PROMUS Element Stent in small vessels and long lesions. The small vessel study will examine lesions from 2.25 to 2.50 mm in diameter and less than or equal to 28 mm in length, while the long lesion study will examine lesions from 2.50 to 4.25 mm in diameter and 24 to 34 mm in length. The primary endpoint of both studies is TLF at 12 months.

The PROMUS Element Stent is an investigational device and is limited by applicable law to investigational use only and is 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.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

Web site: http://www.bostonscientific.com/

---