

Boston Scientific

## **Boston Scientific Announces Start of Major European Registry Assessing Different Olimus-Eluting Stents**

### **PROENCY will provide real-world clinical data on the PROMUS™ Stent**

PRNewswire-FirstCall  
NATICK, Mass.  
(NYSE:BSX)

NATICK, Mass., Feb. 11 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the first patient has been enrolled in its PROENCY (PROMUS™, ENdeavor® and CYpher®) European registry. The registry is the first to observe different 'Olimus'-eluting coronary stents. It will collect real-life clinical outcome data for Boston Scientific's PROMUS™ Everolimus-Eluting Coronary Stent and compare them with data from Johnson & Johnson's Cypher® Sirolimus-Eluting Stent and Medtronic's Endeavor® Zotarolimus-Eluting Stent in patients in routine clinical practice. The PROMUS Stent is a private-labeled XIENCE™ V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific. The PROMUS Stent is an investigational device in the United States with its Premarket Approval (PMA) application currently under review by the U.S. Food and Drug Administration.

"I am excited to enroll the first patient into this innovative new registry," said Professor Christian Hamm, Principal Investigator, Kerckhoff Heart Center, Bad Nauheim, Germany. "We have previously seen efficacy data from clinical trials with the PROMUS, Cypher and Endeavor stents but data from this registry will allow us, for the first time, to comparatively assess the differences between everolimus-, sirolimus- and zotarolimus-eluting stents in patients with simple and complex lesions. This should help clinicians in making the appropriate stent choice for their patients."

The registry will enroll up to 2,500 patients with simple and complex lesions at multiple sites in several European countries. Of the patients at each site, half will receive the PROMUS Stent and half will receive either the Cypher or the Endeavor Stent to attain a 2:1:1 ratio of PROMUS, Cypher, and Endeavor Stents respectively. The primary endpoint of the registry will be the rate of major cardiac events (cardiac death, all myocardial infarction and target vessel revascularization) at 12 months.

The PROMUS, Cypher and Endeavor Stents have previously been investigated in randomized clinical trials. Twelve-month data from the SPIRIT III Trial, presented in October 2007 at the Transcatheter Cardiovascular Therapeutics conference in Washington, confirmed earlier positive clinical results for the XIENCE V (PROMUS) Stent. This trial compared XIENCE V (PROMUS) with the market-leading TAXUS® Express2™ Paclitaxel-Eluting Stent, demonstrating non-inferiority in the primary endpoint of in-segment late loss at eight months with no safety concerns at 12 months.

Boston Scientific is the first company to offer European physicians and their patients a choice of two distinct drug-eluting stent platforms: TAXUS and PROMUS.

TAXUS and PROMUS are trademarks of Boston Scientific Corporation or its affiliates. XIENCE is a trademark of the Abbott Laboratories group of companies. Endeavor is a trademark of Medtronic Vascular Incorporated. Cypher is a trademark of Cordis Corporation, a Johnson & Johnson company.

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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