Boston Scientific

Boston Scientific Announces European Approval of Platinum Chromium TAXUS® Element™ Stent System

NATICK, Mass., May 12 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received CE Mark approval for its TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System, the Company's third-generation drug-eluting stent (DES) technology. This approval includes a specific indication for the treatment of diabetic patients. The TAXUS Element Stent System incorporates a platinum chromium alloy with an innovative stent design and an advanced catheter delivery system. The Company plans to launch the TAXUS Element Stent System next month in the European Union and other CE Mark countries.

"In my experience, the platinum chromium alloy and new stent design used in the TAXUS Element Stent offer increased flexibility, visibility and deliverability," said Dean 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 PERSEUS clinical program. "The Element platform represents a significant advance in coronary stenting with performance improvements that could simplify procedures and allow treatment of a broader range of patients. The combination of the proven TAXUS drug and polymer with the new Element platform provides a welcome treatment option."

"As the worldwide prevalence of diabetes continues to increase dramatically, the diabetic indication for the TAXUS Element Stent System represents an important benefit for diabetic patients being treated for coronary artery disease," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "The TAXUS Element Stent System, with the proven performance of paclitaxel, provides an advanced treatment option for diabetic patients. This product's unique mechanism of action helps to inhibit restenosis in high-risk patients with diabetes, and we are pleased to offer it to these patients."

The TAXUS Element Stent is designed specifically for coronary stenting and leverages the performance advantages of the Element platform with a decade of clinical success from the TAXUS program. The novel stent architecture and proprietary platinum chromium alloy combine to offer greater radial strength and flexibility. The stent architecture helps create consistent lesion coverage and drug distribution while improving deliverability, which is enhanced by an advanced catheter delivery system. The higher density alloy provides superior visibility and reduced recoil while permitting thinner struts compared to prior-generation stents(1).

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

In March, the Company announced 12-month results from its PERSEUS clinical program demonstrating positive safety and efficacy outcomes in workhorse lesions for the TAXUS Element Stent System compared to the TAXUS® Express2™ Stent System. The results also reported a similar safety profile and statistically superior efficacy outcomes in small vessels for the TAXUS Element Stent compared to a historical control group of patients receiving the Express® bare-metal stent.

"The PERSEUS data confirmed that the proven TAXUS drug and polymer combination has been successfully transferred to the Element platform with notable advantages in acute performance," added Kucheman.

The PERSEUS clinical program compared the TAXUS Element Stent to prior-generation Boston Scientific stents in more than 1,600 patients in two parallel trials at 90 centers worldwide.

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

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

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