## Boston Scientific Announces European Launch and First Implants of Platinum Chromium TAXUS® Element<sup>™</sup> Stent System CE Mark approval includes specific indication for treatment of diabetic patients

NATICK, Mass., June 10 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced the market launch and first implants of its TAXUS<sup>®</sup> Element<sup>™</sup> Paclitaxel-Eluting Coronary Stent System in the European Union and other CE Mark countries. The TAXUS Element Stent System is the Company's third-generation drug-eluting stent (DES) technology and incorporates a platinum chromium alloy with an innovative stent design and an advanced catheter delivery system. It received CE Mark approval last month, which included a specific indication for the treatment of diabetic patients.

The first European implants were performed by Corrado Tamburino, M.D., Ph.D., Chair of the Cardiology Department at Ferrarotto Hospital, Catania, Italy and Adrian Banning, M.D., Directorate Chair of Cardiac Services at John Radcliffe Hospital, Oxford, U.K.

"I have found the TAXUS Element Stent to offer performance advantages in flexibility, visibility and deliverability over prior-generation stents," said Dr. Tamburino. "The platinum chromium alloy and new stent design used in the Element platform, together with the proven TAXUS drug and polymer, represent a significant advance in coronary stenting."

"The diabetic indication for the TAXUS Element Stent System provides an important benefit given that approximately one third of all patients presenting with coronary artery disease in Europe have diabetes," said Dr. Banning. "Diabetic patients with coronary artery disease often have poorer outcomes after revascularization procedures. The paclitaxel-based TAXUS Element Stent has a unique mechanism of action that helps inhibit restenosis in high-risk patients with diabetes."

The TAXUS Element Stent is designed specifically for coronary stenting and leverages the performance advantages of the Element Stent 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).

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<sup>®</sup> Express2<sup>®</sup> Stent System. Those results were recently published in the Journal of the American College of Cardiology. The PERSEUS 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<sup>®</sup> bare-metal Stent.

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

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. and Japan, 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: <u>www.bostonscientific.com</u>.

## **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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