

PROMUS® Element™ Stent Approved for Use in Diabetic and Heart Attack Patients in CE Mark Countries

NATICK, Mass., Sept. 21 /[PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced that its PROMUS® Element™ Everolimus-Eluting Coronary Stent System has received CE Mark approval for use in patients with diabetes(1) and those experiencing an acute myocardial infarction (AMI), or heart attack.

"We are pleased to receive these expanded indications for the high-risk diabetic and AMI patient groups," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific's Cardiology, Rhythm and Vascular Group. "The platinum chromium PROMUS Element Stent has been well received by physicians since its launch last year in CE Mark countries, and these new indications are important additions, especially as the prevalence of diabetes continues to increase dramatically worldwide."

Boston Scientific is a leader in the treatment of cardiovascular disease and has the broadest offering of drug-eluting stents and the greatest number of specific patient indications.

The PROMUS Element Stent features a novel platinum chromium alloy and innovative stent design, which combine to offer greater radial strength and flexibility while reducing stent recoil. The stent geometry helps create consistent lesion coverage and drug distribution while improving deliverability, which is enhanced by an advanced catheter delivery system. The higher density platinum chromium alloy provides superior visibility while permitting thinner struts compared to prior-generation stents(2).

The Company received CE Mark approval for the PROMUS Element Everolimus-Eluting Stent System in October 2009 and for the TAXUS® Element™ Paclitaxel-Eluting Stent System in May, which included a specific indication for the treatment of diabetic patients. Both Element 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., 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.

About Boston Scientific

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 27A of the Securities Act of 1933 and 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 new product launches and launch cadence, regulatory approvals, clinical trials, product performance and competitive offerings. 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) For patients with concomitant diabetes mellitus.

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

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