Boston Scientific

PROMUS Element™ and PROMUS Element™ Plus Receive CE Mark Approval for Labeling Update to Include Three-Month Dual Anti-Platelet Therapy

NATICK, Mass., Oct. 24, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE:BSX) has received approval to update the directions for use (DFU) labeling for PROMUS Element™ and PROMUS Element™ Plus Coronary Stent Systems to include three-month Dual Anti-Platelet Therapy (DAPT). This language outlines a minimum duration of three months of DAPT for certain patients who may need to interrupt or discontinue the medication for a variety of reasons and supports the strong safety profile for PROMUS Element and PROMUS Element Plus Stents. The label change will be introduced in CE Mark countries.

"Boston Scientific is pleased to provide this additional guidance in our labeling," said Keith D. Dawkins, M.D., executive vice president and global chief medical officer for Boston Scientific. "However, it remains important to consider the major clinical society guidelines for DAPT post-stent implantation for durable polymer stents."

Current European of Cardiology (ESC) guidelines recommend nine to twelve months of DAPT, with a minimum of six months for those who received a drug-eluting stent (DES). The American Heart Association (AHA) and American College of Cardiology (ACC) recommend up to twelve months of DAPT for DES post-stent implantation.

"This update to our labeling highlights that the need still exists for a drug-eluting stent that reduces the risks associated with long-term durable polymer exposure," said Kevin Ballinger, president of the Interventional Cardiology Division at Boston Scientific. "We believe our next generation SYNERGY™ Stent, with its unique PLGA bioabsorbable polymer, will address that need."

The SYNERGY Stent is unique in that its proprietary PLGA polymer and everolimus drug coating dissipate by three months. This simultaneous drug and polymer absorption is designed to encourage optimal healing, eliminate long-term polymer exposure and potentially lead to reduced long-term events, such as very late stent thrombosis.

The SYNERGY Stent is an investigational device, limited by law to investigational use and is not approved or available for sale in the United States and the European Economic Area.

About Boston Scientific
Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that 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 regulatory approvals, clinical trials and outcomes, product performance and impact, 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.

CONTACT:
Simonetta Balbi
+ 39 3387936422 (mobile)
+ 39 0106060281 (direct)

PR and Corporate Communication EMEA
Boston Scientific
Balbis@bsci.com

Steven Campanini
214-546-5034 (mobile)
Media Relations
Boston Scientific Corporation
steven.campanini@bsci.com

Michael Campbell
508-650-8023 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

SOURCE Boston Scientific Corporation

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