Boston Scientific

Boston Scientific Announces FDA Approval and U.S. Launch of EPIC™ Vascular Stent

New Self-Expanding Nitinol Stent Offers Balance of Flexibility and Radial Strength for Enhanced Performance in Iliac Stenting Procedures

NATICK, Mass., May 17, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces U.S. Food and Drug Administration approval and market launch of the Epic™ Vascular Self-Expanding Stent System. The Epic Stent is designed to open blocked arteries in patients with iliac artery stenosis, a form of peripheral vascular disease associated with severe leg pain caused by insufficient blood flow.

"The Epic Stent System demonstrates an excellent combination of flexibility, radial force and deployment accuracy - all important attributes when treating challenging atherosclerotic lesions in the iliac arteries," said Thomas Shimshak, M.D., medical director at Wheaton Franciscan Heart Care in Racine, WI. "The comprehensive stent size matrix should also help meet a variety of clinical requirements when treating iliac arterial disease with no compromise in deliverability or stent performance."

The Epic Stent is a self-expanding Nitinol stent designed to sustain vessel patency, while providing enhanced visibility and accuracy during placement. It employs an innovative Tandem Architecture™, which is engineered to provide excellent stent flexibility while maintaining predictable radial force characteristics and fracture resistance. The Epic Stent employs distal and proximal radiopaque markers and all stent sizes are compatible with 6F sheaths. The stent delivery system is offered in two shaft lengths (75 cm and 120 cm) for all sizes and is compatible with 0.035" guidewires.

In January, Boston Scientific announced that the ORION trial met its primary clinical endpoint. The Epic Vascular Stent System demonstrated a low nine-month major adverse events (MAE) rate of 3.4 percent in the intent-to-treat population, which was significantly lower than the pre-specified performance goal of 17 percent ($p<0.001$) based on historical published outcomes for iliac stenting.

"The Epic Stent is another example of our commitment to innovation in treating peripheral vascular disease, a growing worldwide health concern," said Jeff Mirviss, president of the Boston Scientific Peripheral Interventions Division. "This next-generation stent expands our growing peripheral interventions portfolio, complementing the leading Express® LD balloon-expandable iliac stent, and offering physicians a versatile new option to treat patients with challenging lesions in the iliac arteries."

Iliac stenosis (narrowing) occurs when plaque accumulates within the arteries that supply blood to the legs, which can lead to poor blood flow, claudication (leg pain) and other complications. The disease can be treated with medication, surgery or angioplasty.

The Epic Vascular Self-Expanding Stent System received CE Mark approval and was launched in Europe and other international markets in 2009.

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 product performance, clinical outcomes, our business plans 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.

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