Boston Scientific Announces CE Mark and European Launch of Innova™ Self-expanding Bare-metal Stent System

NATICK, Mass., May 14, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces CE Mark and European market launch of the Innova™ Self-Expanding Bare-Metal Stent System, which is designed to treat peripheral vascular lesions in arteries above the knee, specifically the superficial femoral artery (SFA) and proximal popliteal artery (PPA). The company plans to launch the product immediately in Europe and other CE Mark countries.

"Treating arteries above the knee is difficult because the challenging anatomy can lead to stent fractures and higher restenosis rates," said Mauro Gargiulo, M.D., physician at Sant'Orsola-Malpighi in Bologna, Italy, who performed the first procedure using the Innova Stent in Europe. "The unique design and stent architecture used in the Innova Stent platform provide excellent radial strength, flexibility and durability which are critical to sustaining patency in treated SFA and PPA lesions. The excellent deliverability and placement accuracy add another significant level of benefit, especially when accessing challenging and long lesions."

The Innova Stent System consists of a Nitinol, self-expanding, bare-metal stent loaded on an advanced low-profile delivery system. The innovative architecture features a closed-cell design at each end of the stent for more consistent deployment, and an open-cell design along the stent body for improved flexibility. Deployment accuracy is enhanced with a tri-axial catheter shaft designed to provide added support and placement accuracy as well as radiopaque markers to enhance visibility. The Innova Stent is 6F compatible and is available in sizes from 5 mm to 8 mm in diameter and 20 mm to 200 mm in length.

"The Innova Stent is engineered to offer an advanced solution to treat blockages within these critical arteries," said Jeff Mirviss, president of Boston Scientific's peripheral interventions division. "This next-generation stent technology is designed to offer physicians improved acute performance and excellent long-term stent durability, intended to improve overall quality of life for patients with peripheral artery disease."

Patient enrollment continues in the SuperNOVA clinical trial to support the company's application for U.S. Food and Drug Administration approval of the Innova Stent System. This prospective, single-arm, non-randomized trial evaluates the safety and effectiveness of the Innova Stent in patients with stenosis of the SFA, PPA, or both. Enrollment is planned for up to 300 patients at 50 sites in the U.S., Canada and Europe, and is expected to be completed in the first half of 2013.

Peripheral vascular disease (PVD) is a circulatory disorder that results from a build-up of plaque in one or more of the arteries of the legs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries, resulting in pain and increasing disability. In Europe, PVD affects 13 million people or one in 20 people over 40 years old.

In the U.S., the Innova Stent System is an investigational device, limited by applicable law to investigational use only and not available for sale.

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 new product launches and launch cadence, regulatory approvals, clinical trials, product performance, clinical outcomes, the market for PVD devices in Europe and our business plans. 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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