Boston Scientific

Boston Scientific Completes Enrollment In SuperNOVA Trial Evaluating Innova™ Self-Expanding Stent System

Innovative Bare Metal Stent Designed to Treat Peripheral Artery Disease

NATICK, Mass., Aug. 19, 2013 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has completed enrollment in the SuperNOVA trial – a global, single arm, prospective, multicenter trial evaluating the long-term (12 month) safety and effectiveness of the Innova™ Self-Expanding Stent System (Innova Stent System). This advanced stent system is designed for treating patients with a narrowing or blockage of the arteries above the knee, often associated with peripheral artery disease (PAD).

The study enrolled 299 patients at 51 sites in the U.S., Canada, Japan and Europe and is expected to support regulatory submissions in the U.S., Canada and Japan.

"Treating vascular lesions in the superficial femoral artery (SFA) and proximal popliteal arteries (PPA) is particularly challenging due to a variety of anatomical factors, including vessel length and tortuosity," said Richard Powell, M.D., section chief, Department of Vascular Surgery, Dartmouth Hitchcock Medical Center, Lebanon, N.H., professor of Surgery and Radiology at Geisel School of Medicine, and global principal investigator of the SuperNOVA trial. "From my experience in the clinical trial, the Innova Stent System offered the design characteristics required for acute and long term success in these challenging vessels, including radial strength, flexibility, fracture resistance and long stent lengths."

The Innova Stent System consists of a Nitinol self-expanding, bare-metal stent loaded on an advanced low-profile delivery system. The stent architecture features a uniform, open-cell structure along the stent body designed for enhanced flexibility, radial strength and fracture resistance and a closed-cell design at each stent end for uniform deployment. The delivery system of the Innova Stent System features a tri-axial delivery catheter with an outer stabilizer sheath engineered to enhance deployment accuracy. The Innova Stent is 6 F compatible and available outside the U.S. in diameters from 5 mm to 8 mm and lengths of 20 mm to 200 mm.

"Peripheral artery disease affects millions of people globally, diminishing their quality of life and putting them at increased risk of limb amputation, stroke, heart attack and even death," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "The Innova Stent System is specifically designed for use in the SFA and PPA and we expect it will provide physicians with a new alternative to treat peripheral artery disease in the challenging vascular environment above the knee."

More than 27 million people worldwide suffer from PAD, a buildup of plaque that narrows and blocks the arteries, reducing blood flow to the limbs. PAD most commonly occurs in the pelvis and legs, sometimes causing symptoms such as cramping, numbness and pain in the calves or thighs while walking. Left untreated, PAD of the lower extremities can lead to painful wounds on the feet and toes, infections or amputation.

The Innova Stent System received CE Mark approval in May 2012. In the U.S., the device is investigational and not available for sale. An image of the Innova Stent System is available for download here.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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 markets for our products, our business plans, regulatory approvals, clinical trials and results, 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.

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