

Boston Scientific Begins International Clinical Trial Enrollment for INNOVA™ Self-Expanding Bare-Metal Stent System

Innovative stent designed to treat peripheral vascular lesions for stenoses in arteries above the knee

NATICK, Mass., April 5, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced the start of patient enrollment in the SuperNOVA clinical trial, an international, prospective, single-arm, non-randomized trial evaluating the safety and effectiveness of the [INNOVA™ Self-Expanding Bare-Metal Stent System](#) in patients with stenosis of the superficial femoral artery (SFA) or proximal popliteal artery (PPA). Enrollment is planned for up to 300 patients at 50 sites in the U.S., Canada and Europe. The first patient was enrolled in the trial last week by Subhash Banerjee, M.D., Associate Professor of Medicine and Chief of Cardiology at the VA Medical Center in Dallas, TX.

The INNOVA Stent System is designed to treat peripheral vascular lesions in arteries above the knee, specifically the SFA and PPA. It 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 improved radial force and fracture resistance, and an open cell design along the stent body that doesn't compromise flexibility. Stent deliverability is enhanced with a tri-axial catheter shaft designed to provide added support and placement accuracy as well as dual deployment options and radiopaque markers to enhance ease of use. The INNOVA Stent is 6F compatible and ranges from 5 mm to 8 mm in diameter and 20 mm to 200 mm in length.

"Treating arteries above the knee is difficult because the challenging anatomy can lead to stent fractures and higher restenosis rates," said Richard J. Powell, M.D., Section Chief of Vascular Surgery at Dartmouth-Hitchcock Medical Center in Lebanon, NH, and Global Principal Investigator of the SuperNOVA trial. "I believe the INNOVA Stent offers a unique design that provides excellent radial strength while remaining flexible and durable, which is critical to sustaining patency in treated SFA and PPA lesions."

"The INNOVA Stent is engineered to offer an advanced solution in treating blockages within these critical arteries," said Joe Fitzgerald, Senior Vice President and President of Boston Scientific's Endovascular Unit. "Its design is intended to improve blood flow and provide greater long-term stent durability, ultimately improving the overall quality of life for patients with peripheral artery disease."

The INNOVA™ Stent System received CE Mark in March, and the Company plans to begin marketing the product in the EU and other countries in the second quarter of 2011. In the U.S., it 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 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.

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