Boston Scientific

Boston Scientific Completes Enrollment in Clinical Trial Evaluating Next-Generation Nitinol Stent to Treat Iliac Artery Disease

NATICK, Mass., Jan. 10, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has completed enrollment in the ORION clinical trial, which is designed to evaluate the Company's EPIC™ Self-Expanding Nitinol Stent System for the treatment of iliac artery disease, a form of peripheral artery disease associated with severe leg pain caused by insufficient blood flow to the muscles (claudication). The trial will examine rates of device- and/or procedure-related major adverse events and patency rates at nine months in 125 patients at 28 sites in the United States.

"We are pleased to complete the enrollment phase of this important trial," said Daniel Clair, M.D., F.A.C.S., Chairman of the Department of Vascular Surgery, The Cleveland Clinic Foundation, and Principal Investigator of the trial. "Peripheral stenting has become a recognized standard in the treatment of iliac artery disease, and the ORION trial will provide important data on the performance of the EPIC Stent in treating these types of lesions."

The next-generation 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 Radial Tandem Architecture™, which is engineered to provide stent flexibility while maintaining predictable radial force characteristics across the entire stent size matrix. The ORION trial incorporates stent diameter ranges from 6 to 12 mm and lengths up to 120 mm. All stent sizes are compatible with 6F (2.1 mm) sheaths, and the stent delivery system is compatible with 0.035 inch (0.89 mm) guidewires.

"We are encouraged by the success of our EPIC Stent since its European approval and launch in early 2009, and we look forward to its approval in the U.S. based on results from this trial," said Joe Fitzgerald, Senior Vice President and President of Boston Scientific's Endovascular Unit. "The EPIC Stent is designed to offer a more balanced stent platform, allowing for excellent radial force without compromising stent flexibility and providing physicians a less-invasive alternative to surgery for treating iliac artery disease."

The EPIC Stent builds on Boston Scientific's long-time leadership in the peripheral intervention market. The Company's peripheral product lines feature technologies used to diagnose and treat peripheral artery disease, including stents, balloon catheters, sheaths, wires, peripheral embolization solutions and vena cava filters. This advanced product portfolio offers physicians a range of peripheral stent indications, including the Carotid WALLSTENT® Endoprosthesis for carotid artery disease and the Express® SD Stent for renal artery disease. Boston Scientific is the only company with a premounted balloon-expandable stent approved by the U.S. Food and Drug Administration for use in treating iliac artery disease -- the Express® LD Iliac Stent.

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

The EPIC Nitinol Stent System is an investigational device and is limited by applicable law to investigational use only and is not available for sale in the U.S.

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.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

Sean Wirtjes
508-652-5305 (office)
Investor Relations
Boston Scientific Corporation

SOURCE Boston Scientific Corporation
