Boston Scientific

Boston Scientific Epic™ Stent Demonstrates Positive Clinical Outcomes in Orion Trial

Nine-month data presented at ISET support safety and efficacy of Epic Stent in iliac stenting

NATICK, Mass. and MIAMI, Jan. 16, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) reports nine-month clinical endpoint data from its ORION trial, demonstrating excellent outcomes for the Company's Epic™ Self-Expanding Nitinol Stent System in patients with iliac artery disease, a form of peripheral artery disease associated with severe leg pain caused by insufficient blood flow. Results were presented today by Daniel Clair, M.D., FACS, Principal Investigator of the trial and Chairman of the Department of Vascular Surgery, The Cleveland Clinic Foundation, at the International Symposium on Endovascular Therapy (ISET) in Miami.

"Peripheral stenting has become a recognized standard in the treatment of iliac arterial disease to restore blood flow in blocked leg arteries," said Dr. Clair. "Outcomes from the ORION trial support both the safety and efficacy of the Epic Stent and confirm its excellent performance in the treatment of atherosclerotic lesions in iliac arteries."

The prospective, single-arm ORION trial enrolled 125 patients at 28 sites in the U.S. The trial met its primary endpoint, a composite rate of device- and/or procedure-related major adverse events (MAE) at nine months. MAE are defined as death within 30 days, myocardial infarction (MI, or heart attack) occurring during hospitalization, target vessel revascularization (TVR) through nine months and amputation of the treated limb through nine months. The Epic Stent demonstrated a low nine-month 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. All reported major adverse events were related to TVR. No deaths through 30 days and no amputations through nine months were observed.

Patients experienced significant clinical improvement from baseline to nine months based on feedback from validated questionnaires evaluating walking distance, speed and stair climbing. An additional measure of effectiveness based on the Rutherford Classification showed improvement in the patient population from 7.2 percent being asymptomatic or having mild claudication (class 0-1) at baseline to 82.3 percent of patients at 30 days and 81.6 percent at nine months. Duplex ultrasound showed a primary patency of 95.9 percent, primary-assisted patency of 96.7 percent and secondary patency of 98.3 percent, indicating that treated lesions remained open through the nine-month follow-up period.

"We are pleased to report positive outcomes for U.S. patients in the ORION clinical trial. The Epic Stent has been used successfully in Europe for several years and we look forward to offering the device to U.S. physicians upon FDA approval," said Jeff Mirviss, President of Boston Scientific's Peripheral Interventions business. "The Epic Stent is a novel stent platform designed to offer both acute and clinical advantages over older-generation stent systems. Upon approval, the Epic Stent along with the market-leading Express® LD balloon-expandable iliac stent, would enable Boston Scientific to offer a complete line of advanced iliac solutions for physicians and patients."

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 across the entire stent size matrix. The Epic Stent is compatible with 6F sheaths, and the stent delivery system is compatible with 0.035 inch guidewires.

ORION clinical data is being used to support application for U.S. Food and Drug Administration (FDA) approval of the Epic Stent system, which was submitted to the FDA in September 2011.

The Epic Nitinol Stent System received CE Mark approval and was launched in Europe and other international markets in 2009. 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 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 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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