Boston Scientific

Boston Scientific Begins Clinical Trial for Next-Generation Nitinol Stent to Treat Iliac Artery Disease

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NATICK, Mass., May 20 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced the start of patient 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 that impacts a patient's lower extremities. The first U.S. patient was enrolled on May 14 by Nicolas W. Shammas, M.D., at Trinity Terrace Park Hospital in Bettendorf, Iowa.

"Peripheral stenting has become a recognized standard in the treatment of iliac arterial disease," said Daniel Clair, M.D., FACS, Principal Investigator of the trial and Chairman of the Department of Vascular Surgery, The Cleveland Clinic Foundation. "The ORION clinical trial will provide important data on the performance of the EPIC Stent in the treatment of atherosclerotic lesions in iliac arteries."

"We are encouraged by the early positive response to our EPIC Stent in Europe, where it was launched last month, and we are pleased to begin the process of evaluating it for use in the United States," said Donald S. Baim, M.D., Chief Medical and Scientific Officer of Boston Scientific. "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 new option for treating iliac disease."

The EPIC Stent is a self-expanding nitinol stent designed to sustain vessel patency (openness), while providing enhanced visibility during placement. The ORION trial incorporates stent diameter ranges from 6-12 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'' (0.89 mm) guidewires.

The trial will enroll 123 patients at 25 sites in the U.S. and will examine rates of device- and/or procedure-related major adverse events (MAE) at nine months. MAE are currently defined as death within 30 days, myocardial infarction (MI, or heart attack) occurring during related hospitalization, target vessel revascularization (TVR) through nine months and amputation of the treated limb through nine months.

The EPIC Stent is a next-generation product that builds on Boston Scientific's long-time leadership in the peripheral interventions market. The Company's peripheral product lines feature technologies used to diagnose and treat peripheral 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.

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.

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 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 clinical trials, regulatory approvals, competitive offerings and product performance. 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 thereafter. 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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