Boston Scientific

Boston Scientific Announces Launch of Expanded Size Range of FilterWire EZ™ Embolic Protection System

NATICK, Mass., May 19 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced the launch of its FilterWire EZ™ Embolic Protection System in a new 2.25 - 3.5 mm size, designed to contain and remove embolic material that may be dislodged during an interventional saphenous vein graft (SVG) procedure; otherwise, embolic material may travel into the microvasculature where it could pose an increased risk for a heart attack. The Company said the product would be available immediately.

"Recently revised treatment guidelines by the American College of Cardiology have recommended the use of embolic protection devices when treating patients with SVG disease(1)," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular for Boston Scientific. "Until now, a filter-based solution smaller than 3.0 mm was not available for SVGs, which meant a significant patient population went underserved. By introducing this smaller size, Boston Scientific now makes it possible for physicians to meet this standard of care in a broader range of SVG vessels."

The FilterWire EZ System is a low-profile embolic protection device that has been clinically proven to capture and remove embolic material, leading to reduced complications during balloon angioplasty and stenting procedures in SVGs(2). SVG disease occurs in patients who have previously had coronary artery bypass graft (CABG) surgery in which a vessel harvested from the patient's leg is surgically attached to the arteries of the heart. Blood is redirected through the surgically attached SVG, bypassing the blocked artery and increasing blood flow to the heart.

The complex nature and progression of SVG disease as compared to native coronary artery disease can create a challenging treatment situation for physicians and a higher risk for patients. In Boston Scientific's BLAZE II study, which evaluated the safety and performance of the FilterWire EZ System's 2.25 - 3.5 mm size, a 30-day major adverse cardiac event (MACE) rate of 4.6 percent was reported, with MACE defined as death, myocardial infarction, emergent CABG or revascularization. The study also resulted in no deaths, no target lesion revascularizations (re-interventions) and no sub- acute thrombosis (clots) during the 30-day follow-up period. The BLAZE II study involved 131 patients in 16 sites in the United States.

"Despite the complexity of treating smaller vessel SVGs, this study presented excellent safety and efficacy data," said Kucheman. "That should give physicians great confidence when treating the unpredictable SVGs they see in their practice every day."

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: http://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, product performance and our market position. 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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(1) Smith SC Jr, et al., Circulation 2006; 113:156-175.
(2) Stone GW, et al., Circulation 2003; 108:548-553.

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