Boston Scientific

FDA Approves Boston Scientific's Carotid Artery Stent

PRNewswire-FirstCall
NATICK, Mass.

NATICK, Mass., Oct. 23 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved its Carotid WALLSTENT® Monorail® Endoprosthesis for the treatment of patients with carotid artery disease who are at high risk for surgery. The Carotid WALLSTENT Endoprosthesis is the leading carotid stent in Europe and other international markets. The Company said it plans to launch the product immediately in the United States.

"We are pleased to bring this proven technology to physicians in the United States," said Hank Kucheman, Senior Vice President and Group President of Boston Scientific's Cardiovascular business. "Excellent patient outcomes and ease of use in complex anatomy have already made this system the number-one stenting option for treating carotid artery disease in Europe and other countries outside the U.S. It offers a less-invasive alternative to surgery for treating carotid artery disease, and can help reduce the risk of stroke, which can have devastating effects."

The Carotid WALLSTENT is a self-expanding stent mounted on a rapid exchange delivery system, designed to re-open the carotid artery by treating stenoses, and improve blood flow to the brain. The stent features a closed-cell design, engineered for excellent lesion coverage and angiographic results. The system is designed to be highly deliverable and provide access to the toughest lesions.

It is used in conjunction with the FilterWire EZ™ Embolic Protection System, which is designed to capture plaque debris released during the stenting procedure, preventing it from traveling to the brain, where it could create an increased risk for stroke. The device features simplified filter sizing - accommodating vessel diameters between 3.5 mm and 5.5 mm - and offers efficient preparation, deployment and retrieval.

"The closed-cell design of the Carotid WALLSTENT Endoprosthesis is intended to provide increased scaffolding for optimal lesion coverage and a smooth inner lumen," said Barry T. Katzen, M.D., Medical Director, Baptist Cardiac and Vascular Institute, Miami. "This feature will make the Carotid WALLSTENT an attractive new treatment option for U.S. physicians and their patients."

The Carotid WALLSTENT Endoprosthesis with the FilterWire EZ System is the only carotid artery stent system approved in the United States with an indication that includes the treatment of bilateral carotid artery disease (blockages in the carotid arteries on both sides of the neck).

The carotid arteries are the main conduits through which blood flows from the heart to the brain. Carotid artery disease occurs when fatty plaque builds up inside the vessels, causing them to harden and narrow, which increases the risk of stroke. Most patients with carotid artery disease are treated with carotid endarterectomy, a surgical procedure involving an incision in the neck and removal of the plaque from the vessel walls. Carotid artery stenting is a less-invasive alternative in which a stent is delivered to the site of the blockage and expanded, forcing open the walls of the arteries and restoring blood flow.

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 our product performance, regulatory approval of our products, new product launches, competitive offerings, our growth strategy, 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.

SOURCE: Boston Scientific Corporation

CONTACT: Paul Donovan, +1-508-650-8541 (office), +1-508-667-5165 (mobile), Media Relations, or Larry Neumann, +1-508-650-8696 (office), Investor Relations, both of Boston Scientific Corporation

---