

Boston Scientific

Boston Scientific Carotid Artery Stenting Trials Produce Positive Three-Year Results

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(NYSE:BSX)

NATICK, Mass. and WASHINGTON, Oct. 23 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced positive three-year results from its CABERNET and BEACH carotid artery stenting clinical trials. The studies evaluated the effectiveness of stenting with embolic protection for patients at high risk for carotid endarterectomy (CEA), the surgical treatment for carotid artery disease. The three-year CABERNET and BEACH results were presented by L. Nelson Hopkins, M.D., Chairman of Neurosurgery, Department of Neurosurgery, State University of New York, Buffalo, NY, at the annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

Dr. Hopkins reported that the CABERNET major stroke rate was 1.3% at 30 days and 2.8% at three years. The reported BEACH major stroke rate was 1.7% at 30 days and 8.1% at three years. According to the three-year CABERNET data, the ipsilateral stroke rate (a stroke occurring on the treated side of the neck) was 2.9% at 30 days and by three years had only increased to 4.9%. In the BEACH trial, the ipsilateral stroke rate was 3.1% at 30 days and by three years had only increased to 7.7%.

"The three-year results suggest not only an immediate benefit for patients treated with Boston Scientific's NexStent® Carotid Stent and FilterWire EZ™ Embolic Protection System, but also a longer-term benefit in reducing the incidence of stroke over time," said Dr. Hopkins, Co-Principal Investigator of the CABERNET and BEACH clinical trials. "In particular, the CABERNET three-year trial results are very encouraging and continue to demonstrate the long-term efficacy and durability associated with Boston Scientific's NexStent Carotid Stent when used with the Company's FilterWire EZ Embolic Protection System in treating patients at high risk for carotid endarterectomy."

The CABERNET clinical trial was designed to evaluate the safety and efficacy of Boston Scientific's NexStent Carotid Stent and FilterWire EZ Embolic Protection System, while the BEACH clinical trial was designed to evaluate the safety and efficacy of the Company's Carotid WALLSTENT® Monorail® Endoprosthesis and FilterWire EZ Embolic Protection System. CABERNET and BEACH were both prospective, non-randomized, single-arm clinical trials enrolling 454 patients and 480 patients, respectively, who were at high risk for CEA.

"We continue to be excited about the favorable results being reported from the CABERNET and BEACH trials now out to three years," said John Pedersen, President of Peripheral Interventions of Boston Scientific. "The three-year data provide further evidence of the benefits of the NexStent Carotid Stent and FilterWire EZ Embolic Protection System in treating patients at risk for stroke, as well as the potential clinical benefits of Carotid WALLSTENT Endoprosthesis. These trials are indicative of our commitment as a Company to evaluate the long-term safety and efficacy of our products in treating carotid artery disease."

The NexStent Carotid Stent is a closed cell, nitinol stent with a rolled sheet design that enables one stent size to adapt to multiple diameters in tapered or non-tapered vessel configurations. The Carotid WALLSTENT Endoprosthesis is a self-expanding stent with a braided, closed cell design. Closed-cell configurations are designed to increase lesion coverage and provide a smooth inner lumen to help facilitate delivery and retrieval of ancillary devices. The FilterWire EZ System -- an advanced technology designed for simplicity and effectiveness -- captures debris efficiently, simplifies filter sizing and is easy to deliver and retrieve. When compared to surgical alternatives, this system provides a less-invasive way to treat patients with carotid artery disease.

The U.S. FDA has approved the NexStent Carotid Stent and FilterWire EZ Embolic Protection System for use in patients with carotid artery disease who are at high risk for CEA. The Carotid WALLSTENT Endoprosthesis is an investigational device currently under FDA review and is subject to investigational use only under U.S. Federal law.

The carotid arteries, located on either side of the neck, are the main conduit for blood flow to the brain. Plaque formation in these arteries can lead to carotid occlusive disease, putting patients at risk for stroke. Stroke is the third leading cause of death in the United States, killing nearly 160,000 Americans every year, and is the leading cause of serious, long-term disability 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: <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, product performance, competitive offerings and regulatory approvals. 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.

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

Dan Brennan
508-650-8538 (office)
617-459-2703 (mobile)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Media, Paul Donovan, +1-508-650-8541 (office), +1-508-667-5165 (mobile), or Investors, Dan Brennan, +1-508-650-8538 (office), +1-617-459-2703 (mobile), both of Boston Scientific Corporation

Web site: <http://www.bostonscientific.com/>

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