Boston Scientific

# Boston Scientific Initiates Carotid Stent Clinical Study

*First patient enrolled in Carotid WALLSTENT® Endoprosthesis registry*

NATICK, Mass., Dec. 18 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today announced enrollment of the first patient in the CABANA post-market approval study of the Company's Carotid WALLSTENT® Monorail® Endoprosthesis used in conjunction with its FilterWire EZ™ Embolic Protection System. The first patient was enrolled in the CABANA Study by Rajesh M. Dave, M.D., Chairman, Endovascular Medicine, Pinnacle Health Heart and Vascular Institute, Harrisburg Hospital, Harrisburg, PA.

The CABANA Study is a multi-center, U.S. surveillance registry designed to enroll a minimum of 1,000 patients at up to 150 sites. The objective of the study is to compile early clinical outcomes data for the Carotid WALLSTENT Monorail Endoprosthesis and FilterWire EZ Embolic Protection System in routine clinical practice. The U.S. Food and Drug Administration (FDA) approved the Carotid WALLSTENT on October 23, 2008. The FilterWire EZ Embolic Protection System received FDA clearance for use in carotid artery stenting procedures on December 14, 2006.

"We are pleased to be part of this study, which follows recent FDA approval of the Carotid WALLSTENT with the use of the FilterWire EZ Embolic Protection System," said Christopher J. White, M.D., Chairman, Department of Cardiovascular Diseases, Ochsner Clinic Foundation, New Orleans, and Principal Investigator of the study. "We expect that the user-friendly design and ease of use will contribute to improved outcomes in patients with carotid artery stenosis who are at increased risk for carotid surgery."

The Carotid WALLSTENT Monorail Endoprosthesis is a self-expanding stent with a closed-cell design to promote increased scaffolding for excellent lesion coverage and a smooth inner lumen. It features a highly flexible, low-profile stent delivery system designed to provide exceptional tracking through difficult anatomy. The FilterWire EZ Embolic Protection System is designed to capture plaque debris that may be released during a procedure, preventing it from traveling to the brain, where it could cause a stroke. The Carotid WALLSTENT Endoprosthesis and Filter Wire EZ System is the only carotid artery stent system indicated in the United States for the treatment of certain patients at high risk for surgery with either ipsilateral or bilateral carotid artery disease (blockages in carotid arteries on one or both sides of the neck).

"Following the successful results of the BEACH Trial, which supported our application for FDA approval, we are looking forward to the outcome of the CABANA Study in evaluating the real-world safety and performance of the Carotid WALLSTENT Endoprosthesis in conjunction with the FilterWire EZ System," said Hank Kucheman, Senior Vice President and Group President, Cardiovascular. "These studies provide additional evidence of our commitment to demonstrate the safety and efficacy of our products in treating carotid artery disease."

The BEACH Trial was a prospective, non-randomized, single-arm clinical trial with 480 patients, which demonstrated the safety and efficacy of the Carotid WALLSTENT Monorail Endoprosthesis and FilterWire EZ Embolic Protection System. These patients were considered high risk for carotid endarterectomy (CEA), the surgical treatment for carotid artery disease, because they had either anatomical issues (related to the anatomy of the neck, such as tight, tortuous vessels) or co-morbidity (multiple risk factors such as age, angina and heart failure). The primary endpoint in the BEACH trial was one-year morbidity and mortality defined as the cumulative incidence of non Q-wave myocardial infarction within 24 hours of the index procedure, peri-procedural (less than or equal to 30 days) death, stroke and Q-wave myocardial infarction and late ipsilateral stroke and neurological death from 31 days through 12-month follow-up. The one-year morbidity and mortality rate reported in the BEACH trial was 8.9 percent. The reported BEACH ipsilateral stroke rate (a stroke occurring on the treated side) was 3.3 percent, while the major ischemic stroke rate was 1.1 percent at 30 days.

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, 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 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

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

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