Boston Scientific

Boston Scientific Carotid WALLSTENT® Found Safe in Study of High Surgical Risk Patients in Routine Clinical Practice

NATICK, Mass. and SAN FRANCISCO, Nov. 8, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) reports positive outcomes from the CABANA post-approval study of the Carotid WALLSTENT® Monorail® Endoprosthesis used in conjunction with its FilterWire EZ™ Embolic Protection System in routine clinical practice. Multi-center registry results demonstrate that carotid artery stenting (CAS) with Carotid WALLSTENT and FilterWire EZ is a safe alternative to carotid endarterectomy (CEA) in patients with carotid artery stenosis who are at increased risk for surgery. The analysis was presented today by L. Nelson Hopkins, M.D., Chairman of Neurosurgery at the State University of New York in Buffalo, Trial Investigator and Advisory Committee member, at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Francisco.

The CABANA study enrolled 1,097 patients at 99 sites in the U.S. Within the patient population, 32.7 percent were symptomatic and 67.3 percent were asymptomatic for carotid artery disease. All patients were at high risk for CEA, the standard surgical treatment for carotid stenosis, due to pre-specified anatomical criteria and/or medical comorbidities. The primary endpoint of 30-day composite rate of major adverse events (MAE), which included stroke, death and myocardial infarction (MI), was 4.6 percent. The 30-day stroke rate was 3.3 percent, with the majority of strokes being ipsilateral (occurring on same side as blockage) and ischemic (resulting from lack of blood flow). Overall mortality was 1.3 percent and the rate of MI was 0.5 percent at 30 days. Technical success was achieved in 97.1 percent of patients. Follow-up at 30 days included clinical evaluation and independent neurologic and National Institutes of Health (NIH) stroke scale assessments.

"Results from this post-approval study show low rates of stroke, death, and MI, demonstrating that the Carotid WALLSTENT and FilterWire EZ can be used in carotid stenting procedures as a safe alternative to surgery in high-risk patients," said Dr. Hopkins. "In my clinical practice, I have found that the user-friendly design of this stenting system contributes to successful outcomes in patients with carotid artery stenosis at increased risk for surgery."

The Carotid WALLSTENT Monorail Endoprosthesis is a self-expanding stent with a closed-cell design to provide increased scaffolding for improved 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 Monorail Endoprosthesis is the leading carotid stent in Europe and is available in all major markets worldwide.

"As public discussion continues regarding carotid stenosis therapy, the CABANA study demonstrates our commitment to providing physicians with safe and effective CAS treatment options supported by strong clinical evidence," said Jeff Mirviss, President of Boston Scientific's Peripheral Interventions business. "The Carotid WALLSTENT and FilterWire EZ System offer a less-invasive alternative for treating carotid artery disease and can help reduce the risk of stroke, which can have devastating consequences on patients and their families."

The U.S. Food and Drug Administration (FDA) approved the Carotid WALLSTENT in 2008. The FilterWire EZ Embolic Protection System received FDA clearance for use in carotid artery stenting procedures in 2006.

About Carotid Artery Disease

The carotid arteries, located on either side of the neck, are the main conduit for blood supply to the brain. Plaque formation in these arteries can lead to carotid artery disease, which puts patients at increased risk for stroke. Patients with carotid artery disease are typically treated with carotid endarterectomy, a surgical procedure involving an incision in the neck and removal of plaque from the vessel walls. Carotid artery stenting is a less-invasive alternative in which a stent is delivered to the blocked site and expanded, forcing open the artery walls and restoring adequate blood flow.

About Boston Scientific

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 27A of the Securities Act

of 1933 and 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 business plans, our Carotid WALLSTENT® Monorail® Endoprosthesis and FilterWire EZ™ Embolic Protection System, clinical trials, product performance and effects 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 hereafter. 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: Erik Kopp
508-650-8660 (office)
Media Relations
Boston Scientific Corporation
erik.kopp@bsci.com

David Knutson (attending TCT)
651-260-8288 (mobile)
Media Relations
Boston Scientific Corporation
david.knutson@bsci.com

Sean Wirtjes
508-652-5305 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

SOURCE Boston Scientific Corporation
