Boston Scientific

# Boston Scientific Announces Excellent Results in Study of Patients with Carotid Artery Disease

(April 27, 2005) -- Boston Scientific (NYSE: BSX) today announced one-year data from its carotid artery stenting (CAS) clinical trial known as BEACH. The study evaluates the effectiveness of stenting with embolic protection for patients who are at high-risk for carotid endarterectomy (CEA), the surgical treatment for carotid artery disease. Results were presented at the 14th Annual Peripheral Angioplasty and All that Jazz meeting in New Orleans by Christopher White, M.D., Co-Principal Investigator of the trial and Director of the Ochsner Heart and Vascular Institute in New Orleans and Chairman of Ochsner's Department of Cardiology.

The BEACH trial was designed to evaluate Boston Scientific's Carotid WALLSTENT® Monorail® Endoprosthesis (Carotid WALLSTENT) and the FilterWire EX™ and EZ™ Embolic Protection Systems. It is a prospective, non-randomized, single-arm clinical trial that enrolled 747 patients at 47 U.S. sites, with 480 patients in the pivotal phase of the trial. The trial also enrolled 189 patients in a "roll-in" group and 78 patients in a bilateral registry.

The trial has a composite primary endpoint of cumulative mortality and morbidity through one year, consisting of stroke, death and myocardial infarction (MI). Dr. White presented data showing a composite one-year endpoint of 9.1 percent. The breakdown of patients experiencing one or more events is as follows: stroke, 7.0 percent; death, 3.2 percent; and MI, 1.1 percent.

Event rates were similar for the roll-in group and bilateral registry. The roll-in group -- in which physicians trained on the Boston Scientific devices before entering the pivotal group -- reported an event rate of 8.7 percent. The bilateral group -- consisting of patients with carotid artery disease requiring treatment in both carotid arteries -- reported an event rate of 7.1 percent. Bilateral patients are more difficult to treat than patients with carotid artery disease in only one artery, and have largely not been studied as standalone populations in previous trials. The BEACH results suggest that CAS may ultimately be a viable treatment option for this high-risk population.

"These results are well within the trial objectives we hoped to meet," said Dr. White. "They suggest that carotid artery stenting with embolic protection is a viable treatment option in the high-risk patients represented by this study. The roll-in results suggest there is a minimal additional learning curve in this complex patient subset, which is important information when planning physician training and ensuring patient safety."

"Boston Scientific's carotid artery stenting program is one of our top priorities for improving the quality of patient care through less-invasive devices and procedures," said Paul LaViolette, Boston Scientific Chief Operating Officer. "The BEACH results provide important clinical data supporting the safety of the Carotid WALLSTENT. This is good news for clinicians and their patients, and will help our efforts to eventually make this technology available in the United States."

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 artery disease, placing these patients at risk for stroke. Most patients with a narrowing of their carotid arteries are treated by carotid endarterectomy, which involves a vertical incision in the neck through which the plaque is removed. Carotid artery stenting is a less-invasive alternative in which a stent is delivered to the site of the blockage on a catheter. At the site of the blockage, the stent is expanded where it forces the walls of the arteries open, allowing blood flow to resume.

The Carotid WALLSTENT is a self-expanding stent with a braided, closed cell design. The FilterWire EZ Embolic Protection System is a low-profile filter mounted on a Monorail deployment system designed to capture embolic debris released during a procedure and prevent it from traveling to the brain, where it could cause a stroke. Both devices independently carry the CE Mark and are commercially available in Europe and certain other international markets, where they are the CAS market leaders. The Carotid WALLSTENT is an investigational device in the United States and is limited by U.S. law to investigational use. The safety and effectiveness of the FilterWire EZ and EX Embolic Protection Systems for use in carotid arteries has not been established in the U.S. and is currently investigational.

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.

This press release contains forward-looking statements. The Company wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with litigation, clinical trials, the regulatory approval process, reimbursement policies, commercialization of new technologies, intellectual property, and other factors described in the Company's filings with the Securities and Exchange Commission.

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