Boston Scientific

Boston Scientific Study Shows Excellent Performance in High-Risk Patients with Carotid Artery Disease

(October, 17, 2005) -- Boston Scientific Corporation (NYSE: BSX) today presented data from its BEACH clinical trial, which was designed to evaluate the benefits of carotid artery stenting (CAS) in conjunction with embolic protection for the treatment of carotid artery disease. Results were presented at the Transcatheter Cardiovascular Therapeutics symposium, in Washington, D.C.

The study demonstrated that Boston Scientific…amp;trade;s Carotid WALLSTENT¦amp;reg; Monorail¦amp;reg; Endoprosthesis, used in combination with the Company…amp;trade;s FilterWire EX¦amp;reg; and FilterWire EZTM Embolic Protection Systems, improved blood flow within the vessel and the vessel remained open up to one year post-procedure in patients at high risk for surgery (carotid endarterectomy).

“This data shows that CAS using the Carotid WALLSTENT Endoprosthesis and FilterWire System may offer a safe and durable treatment strategy in high-risk patients with carotid artery disease,‿ said Michael R. Jaff, D.O., Assistant Professor of Medicine at Harvard Medical School and Medical Director of the Vascular Ultrasound Core Laboratory, Massachusetts General Hospital.

Dr. Jaff…amp;trade;s staff analyzed all of the duplex ultrasound studies performed in the BEACH trial. “These results show not only that the Carotid WALLSTENT Endoprosthesis improves blood flow through one year in most patients, but also that the performance of the stent can be safely and accurately analyzed by ultrasonography, a non-invasive technique in a multi-center prospective registry,‿ he said.

“Boston Scientific…amp;trade;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 John Pederson, President of Boston Scientific's Peripheral Interventions business. “We are encouraged by the BEACH results, which provide valuable clinical data for these important technologies.‿

BEACH 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 has a composite primary endpoint of cumulative mortality and morbidity through one year, consisting of stroke, death and myocardial infarction (MI). All patients underwent carotid duplex ultrasonography (CDUS) before, immediately after and at one, six and 12 months after CAS. As reported previously, cumulative mortality and morbidity were 5.6 percent at 30 days and 9.1 percent at one year.

Blocked carotid arteries impede blood flow and make it more difficult for the circulatory system to deliver blood to the brain. The velocity of blood flow traveling through a narrowed artery increases just as the velocity of water increases through the narrowed opening of a garden hose. Duplex ultrasonography gives the physician the ability to non-invasively measure the velocity of blood flow, and in a properly treated artery, the velocity markedly decreases. According to data in this analysis, blood velocity in the carotid artery was reduced by more than half during the pumping phase of the heart (peak systolic velocity) up to a year after implantation. The device also reduced blood velocity in the carotid artery nearly three-fold during the relaxation phase of the heart (end diastolic velocity) up to a year after implantation. Although velocity measurements at 12 months were statistically greater than those observed immediately post-procedure, there were no clinically relevant changes in stent patency and there was no increase in neurological events or need for repeat intervention. In addition, improvements in blood flow were stable between six and 12 months.

Analysis Demonstrates Need for Improved Medicare Payment

According to an additional analysis of the BEACH trial data presented at TCT, significant resources were used in providing interventional treatments to patients with carotid artery stenosis. These patients were hospitalized for a median of two days overall and the two symptomatic subgroups experienced longer procedure times. The resource use associated with these types of cases would not be appropriately addressed by Medicare payments. Under the Centers for Medicare and Medicaid Services (CMS) National Coverage Decision (NCD) for CAS, symptomatic patients at high risk for carotid endarterectomy (CEA) and with carotid artery stenosis of ≥70 percent are covered for approved CAS devices implanted at a credentialed facility.

“Boston Scientific…amp;trade;s goal is to help ensure that patient access to carotid artery stenting is facilitated by appropriate payment for physicians and hospitals,‿ said Pedersen. “To help achieve this goal, we seek to provide CMS with data on resources used during CAS so it has the information relevant to make informed payment decisions.‿

Carotid artery stenosis occurs when fatty deposits (plaque) accumulate in one or both of the carotid arteries, which provide the brain with its main supply of blood. Accumulation of plaque can narrow the arteries so severely that the brain does not receive a sufficient supply of blood. In addition, a piece of plaque may break off and travel to the brain. In either case, a stroke may occur. Each year more than 700,000 Americans have a stroke, the number-three killer and a leading cause of severe, long-term disability in the United States.

The Carotid WALLSTENT Endoprosthesis is a self-expanding stent with a braided wire, closed cell design. The FilterWire EZ

Embolic Protection System is a low-profile filter mounted on a Monorail Catheter 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. Pending PMA approval and 510(k) clearance respectively, the Carotid WALLSTENT Monorail Endoprosthesis and FilterWire EX/EZ Embolic Protection Systems, for use in the carotid vasculature, are investigational devices and limited by U.S. law to investigational use by qualified investigators only. Not available for sale 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: www.bostonscientific.com. For information specific to carotid artery disease, please visit: www.carotid.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 new product development and introduction, clinical trials, regulatory approvals, competitive offerings, commercialization of new technologies, intellectual property, the company…amp;trade;s overall business strategy and other factors described in the Company…amp;trade;s filings with the Securities and Exchange Commission.
