Boston Scientific

Boston Scientific Reports Positive Results for its Carotid Artery Stenting Trial

NATICK, Mass. and WASHINGTON, Oct. 23 /PRNewswire-FirstCall/ -- Boston Scientific (NYSE: BSX) today announced two-year data from its BEACH carotid artery stenting (CAS) clinical trial. 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. The results were presented at the Cardiovascular Research Foundation's (CRF) eighteenth annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

The BEACH trial was designed to evaluate Boston Scientific's Carotid WALLSTENT® Monorail® Endoprosthesis and the FilterWire EX® Embolic Protection System and later the FilterWire EZ™ Embolic Protection System. It is a prospective, non-randomized, single-arm clinical trial that enrolled 480 patients in the pivotal phase of the trial. These patients were considered high-risk for surgery because they had either anatomical (issues related to the anatomy of the neck such as tight, tortuous vessels) or co-morbid (multiple risk factors such as age, angina, heart failure) factors making surgery too risky.

The BEACH study's two-year results continue to evaluate long-term safety and efficacy. The ipsilateral stroke rate (a stroke occurring on the treated side of the neck) steadily declined from 3.1 percent from 0-30 days, to 2.3 percent from 31 days to one year, to 0.9 percent between one and two years. The BEACH study also demonstrated declining death rates from 7.5 percent through one year to 6.1 percent between one and two years. In addition, long-term efficacy was evaluated with ultrasound data indicating a continued reduction in mean maximum peak systolic velocity -- when the heart is contracting and therefore pumping the hardest. The progressive reduction in velocity from 346 cm/sec before the stenting procedure to 130 cm/sec out to two years post-procedure suggests no progressive restenosis (re-blockage) from 6 months to 2 years.

"Surgery was not an attractive option for these patients who are at increased risk for stroke," said Christopher White, MD, co-principal investigator of the BEACH study. "These results are encouraging because they suggest Boston Scientific's carotid artery stenting system may not only minimize the risk of stroke after the procedure, but may be a durable treatment with the incidence of stroke declining over time."

The Carotid WALLSTENT Endoprosthesis is a self-expanding stent with a braided, closed cell design. The FilterWire EZ Embolic Protection System is a low-profile filter designed to capture embolic debris released during a procedure and prevent it from traveling to the brain, where it could cause a stroke. The Carotid WALLSTENT Endoprosthesis and FilterWire EZ Embolic Protection System independently carry the CE Mark and are commercially available in Europe and certain other international markets. 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 Embolic Protection System for use in carotid arteries has not been established in the U.S. and is currently investigational.

"Boston Scientific is committed to providing the science, technology and support designed to minimize the devastating effects of stroke," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "The BEACH results demonstrate the dramatic improvement this system could offer patients at risk for stroke, and we look forward to bringing it to physicians 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 pushes the walls of the arteries open, allowing blood flow to resume.

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/.

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.

CONTACT: Milan Kofol
508-650-8569 (office)
617-834-8595 (mobile)
Investor Relations
Boston Scientific Corporation

Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)

Media Relations
Boston Scientific Corporation

SOURCE: Boston Scientific

CONTACT: Milan Kofol, Investor Relations, +1-508-650-8569, mobile: +1-617-834-8595, or Paul Donovan, Media Relations, +1-508-650-8541, mobile: +1-508-667-5165, both of Boston Scientific Corporation

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

---

https://news.bostonscientific.com/positive-results-carotid-artery-stenting-trial