Boston Scientific

# First Patient Enrolled in SONOMA Post-Market Approval Study of Boston Scientific NexStent® Carotid Stent System and FilterWire EZ™ Embolic Protection Device

**Study seeks to confirm the safety and efficacy of systems in routine clinical practice**

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NATICK, Mass., May 31 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced enrollment of the first patient in the SONOMA post-market approval study of the Company's NexStent® Carotid Stent System used in conjunction with the FilterWire EZ™ Embolic Protection System. The SONOMA study is a multi-center, U.S. surveillance registry designed to include a minimum of 1,500 patients at 100 sites. The objective of the study is to confirm the real-world safety and efficacy of the NexStent Carotid Stent System and FilterWire EZ Embolic Protection System in routine clinical practice.

The first patient was enrolled by Subbarao Myla, M.D., Medical Director of Cardiovascular Research and Vascular Intervention, Hoag Heart and Vascular Institute, Hoag Memorial Hospital Presbyterian Newport Beach, CA, and principal investigator of the SONOMA study.

"This study represents one of the few multi-center studies in which shorter-term and longer-term clinical outcomes of carotid artery stenting placement will be reported," said Dr. Myla. "We are hopeful that the unique design and other features of the NexStent Carotid Stent and FilterWire EZ Embolic Protection System will facilitate a high procedure success rate and relatively low risk of major disabling stroke or death in a cohort of patients with symptomatic and asymptomatic carotid artery stenosis that are at high risk for surgery."

All patients enrolled in the SONOMA study are scheduled for follow-up at 30 days and 12 months following stent implantation. In addition, the study will include a cohort of 500 patients whose routine duplex ultrasound evaluations will be reviewed and analyzed by an independent core lab.

The FDA has approved the NexStent Carotid Stent System and FilterWire EZ Embolic Protection System for use in patients with carotid artery disease who are at high risk for surgical carotid endarterectomy. Compared to surgical alternatives, the NexStent Carotid Stent System and FilterWire EZ Embolic Protection System provide a less-invasive way to treat patients with carotid artery disease.

The NexStent Carotid Stent System includes a laser-cut, nitinol stent with a rolled sheet design that enables one stent size to adapt to multiple diameters in tapered or non-tapered vessel configurations. Its self-sizing feature is intended to provide customization when treating lesions in the carotid arteries, while its closed-cell configuration is designed to increase lesion coverage and to provide a smooth inner lumen to help facilitate delivery and retrieval of ancillary devices.

The FilterWire EZ Embolic Protection System is designed to efficiently capture plaque and other material that may dislodge during stent implantation, thereby reducing the risk of procedural-related stroke or heart attack. The system features simplified filter sizing - one size can be placed in vessel

diameters between 3.5 mm and 5.5 mm - and is designed for easy preparation, delivery and retrieval.

The CABERNET Trial demonstrated the safety and efficacy of the NexStent Carotid Stent and FilterWire EZ Embolic Protection System. The study enrolled a total of 454 patients. Follow-up assessment of 438 patients at 30 days showed a stroke rate of 1.3 percent, and a combined stroke, death, and MI rate of 3.9 percent. The stroke, death and MI rate at one year was 4.7 percent (n = 404).

"Following the successful results of the CABERNET Trial that led to FDA approval, we are looking forward to the outcome of the SONOMA study in evaluating the real-world safety and performance of the NexStent Carotid Stent in conjunction with the FilterWire EZ System," said John Pedersen, President of Boston Scientific's Peripheral Interventions business. "It is fitting that SONOMA should be initiated now with the enrollment of the first patient in May, which is Stroke Awareness Month."

Stroke is a leading cause of severe, long-term disability in the U.S. Each year, approximately 700,000 Americans suffer from a stroke. Plaque formation in the carotid arteries can cause the arteries to harden and narrow, impeding blood flow and increasing the risk of stroke in affected patients. Until recently, the only treatment option was to perform carotid endarterectomy, a surgical procedure involving an incision in the neck, opening of the artery and removal of the plaque from the inside of the vessel. Carotid artery stenting is a less-invasive

procedure in which wire access is gained through the femoral artery to the affected area of the carotid arteries and cerebral protection is obtained. A stent is then advanced to the site of the blockage, where it expands and provides scaffolding to open the walls of the arteries, restoring blood flow.

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. Boston Scientific 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 product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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