Boston Scientific

Boston Scientific Announces Completion of Enrollment in Landmark Clinical Trial Comparing Drug-Eluting Stents To Cardiac Surgery

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NATICK, Ma., April 26 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has completed enrollment in its SYNTAX clinical trial. SYNTAX is the first trial to compare the results of drug-eluting stents with those of cardiac surgery in the most complex patient subsets: those with de novo lesions involving all three coronary arteries, in the left main coronary artery, or both. This randomized, controlled clinical trial is designed to compare the 12-month outcomes of such patients after treatment with percutaneous coronary intervention (PCI) using the Company's TAXUS® Express2™ paclitaxel-eluting coronary stent system, versus the current clinical standard of coronary artery bypass graft (CABG) surgery.

Previous studies comparing CABG and PCI have used balloon angioplasty or bare-metal stents, or have been limited to highly selected patient populations, excluding the type of patient enrolled in SYNTAX. In contrast, SYNTAX allowed wide latitude in enrolling these complex patients, with the final decision on whether to randomize a patient being made by the local interventional cardiologist and cardiothoracic surgeon. More than 3,000 patients were enrolled at 85 sites in Europe and the United States.

Patients who were deemed eligible for both treatment options were enrolled in the randomized arm comparing CABG to PCI, which included 1,800 patients (1,090 patients with three-vessel disease and 710 patients with left main (LM) disease). Patients determined to be eligible for only one of the treatment options (PCI or CABG) were enrolled in "nested" registries tracking either CABG or PCI outcomes (more than 1,250 patients combined). The primary endpoint is the 12-month major adverse cardiac and cerebral event rate, which includes death, myocardial infarction, repeat revascularization, and stroke. Results from this randomized arm will provide important clinical information on the relative merits and risks of CABG to PCI in treating complex patients who are eligible for both treatment options. In addition, long-term vascular responses and the relationship of late angiographic outcomes to clinical outcomes will be assessed in a substudy of patients with LM disease randomized to PCI or CABG treatment.

SYNTAX is considered a landmark study that will provide important data regarding the use of DES in these highly complex patients, including patients with three-vessel disease, left main coronary artery disease and patients with diabetes mellitus. The trial's Principal Investigators are Professor Friedrich Mohr, M.D., Program Director of the Heart Center/Cardiothoracic Surgery, University of Leipzig, Germany and Professor Patrick Serruys, M.D., Ph.D., Chief of Interventional Cardiology, Thoraxcenter-Erasmus University Rotterdam, The Netherlands.

In the United States, the TAXUS Express2 coronary stent system is indicated for improving luminal diameter for the treatment of de novo lesions less or equal to 28 mm in length in native coronary arteries greater or equal to 2.5 to less than or equal to 3.75 mm in diameter. The TAXUS stent system has not been approved in the U.S. for the treatment of patients with multi- vessel disease, or in lesions in the left main coronary artery. Additional information about the TAXUS stent system is available at 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 new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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/.

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