Boston Scientific

SYNTAX Data Show Comparable Safety for Complex Patients Treated with TAXUS® Express2™ Stents and Bypass Surgery

New SYNTAX Score shows similar safety and efficacy outcomes for two thirds of study's patients

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NATICK, Mass. and WASHINGTON
(NYSE:BSX)

NATICK, Mass. and WASHINGTON, Oct. 14 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced 12-month left main and three-vessel disease subset data from its landmark SYNTAX trial comparing percutaneous coronary intervention (PCI) using the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System to contemporary coronary artery bypass graft (CABG) surgery. The results reinforced previously announced data demonstrating no overall statistically significant differences between PCI and CABG in rates of death or myocardial infarction (MI). The Company also presented an analysis of the data based on the SYNTAX Score, a new tool that seeks to provide guidance to physicians on optimal treatment options for this high-risk group of patients, showing similar safety and efficacy outcomes for two thirds of SYNTAX randomized patients. The Company made the announcements at the Cardiovascular Research Foundation's (CRF) annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

The SYNTAX trial is the first large scale randomized, controlled clinical trial comparing PCI using drug-eluting stents (DES) to CABG in patients with left main disease and three-vessel disease. These patient groups are typically treated with CABG and represent a population with far more complex anatomy and advanced disease than those studied in prior DES clinical trials. The goal of the trial is to expand the body of knowledge of PCI use and help inform physicians and patients on appropriate treatment options for the sickest patients.

"The data announced today will provide important additional information for doctors as they evaluate treatment options for complex coronary patients," said Keith Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "The comparable safety and efficacy outcomes with PCI and CABG in patients with left main disease in this trial indicate PCI is a good treatment alternative for this patient population. Physicians will also be able to consider the SYNTAX Score analysis, demonstrating no difference in safety and efficacy outcomes between PCI and CABG in approximately two-thirds of the SYNTAX patient population, when assessing the appropriate treatment for their patients."

The SYNTAX Score is breaking new ground by scientifically defining a new measure for anatomical complexity that seeks to provide guidance to physicians on optimal treatment options for this high-risk group of patients. The SYNTAX Score characterizes coronary anatomy based on lesion frequency, complexity and location, relying on data from the SYNTAX trial, and assigns a score to each patient. The analysis of the raw SYNTAX Score data presented today demonstrated that PCI and CABG patients whose scores fell into the lower or intermediate terciles of complexity had similar rates of MACCE (Major Adverse Cardiovascular or Cerebrovascular Event rate, including all-cause death, stroke, MI and repeat revascularization) at 12 months. For patients whose SYNTAX Score fell into the upper tercile -- those with the greatest lesion complexity -- there was a significant increase in MACCE for PCI patients compared with CABG patients.

The 12-month subset results for patients with left main disease reported comparable rates of overall MACCE for the CABG group and the PCI group (13.6 percent for CABG versus 15.8 percent for PCI, p=0.44), as well as similar overall safety outcomes (death, stroke, MI) for the two groups (9.1 percent for CABG versus 7.0 percent for PCI, p=0.29). As expected, the rate of revascularization was significantly higher in the PCI group (12.0 percent for PCI versus 6.7 percent for CABG, p=0.02), while the rate of stroke was significantly higher in the CABG group (2.7 percent for CABG versus 0.3 percent for PCI, p=0.009). The subset results for patients with three-vessel disease reported comparable overall safety outcomes for the two groups (6.4 percent for CABG versus 7.9 percent for PCI, p=0.39), an expected higher rate of revascularization for PCI (14.7 percent for PCI versus 5.4 percent for CABG, p=<0.001) driving higher overall MACCE for the PCI group (19.1 percent versus 11.2 percent for CABG, p=<0.001).

The patients enrolled in SYNTAX are a unique study group in the PCI field, given their exceptionally complex anatomy and advanced disease. The average SYNTAX PCI patient received 4.6 stents, with one patient having 14. By contrast, the average number of stents implanted in a PCI patient in everyday practice is 1.5. In addition, the PCI patient profile includes 33 percent of patients with >100 mm stented length, 73 percent with bifurcations, 11 percent with trifurcations, 22 percent with chronic total occlusions, and 39 percent with left main disease. Some of the sickest patients in the trial were not eligible for surgery and were treated with drug-eluting stents.

The SYNTAX trial enrolled 1,800 patients in its randomized arm, using an innovative consecutive enrollment

methodology. All patients were assessed by a multidisciplinary team including an interventional cardiologist and a cardiac surgeon. If both the cardiologist and surgeon felt they could offer equivalent complete revascularization, patients were randomized 1:1 into one of the two treatment methods (PCI or CABG). If either the cardiologist or surgeon felt that PCI or CABG was the preferred option, then patients were placed in one of two parallel registries for PCI or CABG.

The safety and effectiveness of the TAXUS Express2 Stent System has not been established in patients with left main, multi-vessel disease, chronic total occlusion, lesions at a bifurcation/trifurcation, >28mm in length or requiring multiple stents.

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/.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding clinical trials, regulatory approvals, competitive offerings and product performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A- Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A - Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file thereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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