Boston Scientific

Two-Year SYNTAX Data Show Comparable Safety Outcomes for Complex Patients Treated With TAXUS® EXPRESS® Stents and Bypass Surgery

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NATICK, Mass. and BARCELONA, Spain, Sept. 2 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced two-year data from its SYNTAX clinical trial comparing percutaneous coronary intervention (PCI) using the TAXUS(®) Express(®) Paclitaxel-Eluting Coronary Stent System to coronary artery bypass graft (CABG) surgery. The overall results demonstrated no statistically significant difference between PCI and CABG in the composite safety endpoint (all-cause death, stroke and myocardial infarction [MI]). The Company made the announcement at the annual European Society of Cardiology (ESC) Congress in Barcelona.

"These results reinforce the one-year SYNTAX data and show impressive outcomes for PCI in patients with complex coronary anatomy, the majority of whom are normally treated with CABG surgery," said Keith D. Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "Today's findings build on our prior data and provide additional support for PCI as a viable treatment option for many of these challenging patients."

The patients in the SYNTAX trial - all of whom have left main and/or three-vessel coronary disease - are a unique study group in the PCI field. In the SYNTAX trial, mean stent use was 4.6 stents/patient, with one patient having 14 stents implanted. By contrast, the average number of stents implanted in a PCI patient in everyday practice is 1.5. In addition, the study included 33 percent of patients with >100 mm stented length, 71 percent with bi/trifurcations, 27 percent with chronic total occlusions and 39 percent with left main disease.

The results showed comparable safety profiles for the two treatment groups at two years, with a combined rate of all-cause death, stroke and MI of 10.8 percent for PCI and 9.6 percent for CABG (p=0.44). The rate of stroke was 1.4 percent for PCI as compared to 2.8 percent for CABG (p=0.03), while MI was 5.9 percent for PCI and 3.3 percent for CABG (p=0.01). The rate of all-cause death was 6.2 percent for PCI and 4.9 percent for CABG (p=0.24).

Overall MACCE (Major Adverse Cardiovascular or Cerebrovascular Event rate, including all-cause death, stroke, MI and repeat revascularization) was significantly higher for PCI (23.3 percent as compared to 16.4 percent for CABG, p=0.0002), driven largely by the anticipated higher rate of revascularization in the PCI group (17.4 percent as compared to 8.6 percent for CABG, p<0.0001), with the difference narrowing in the second year of follow-up. Most patients requiring repeat revascularization in the PCI group were successfully treated with another PCI.

The trial results were also analyzed based on the SYNTAX Score, which demonstrated no statistically significant difference in MACCE for patients in the lower two terciles - those with low lesion complexity (19.4 percent for PCI and 17.4 percent for CABG, p=0.63) and moderate lesion complexity (22.8 percent for PCI and 16.4 percent for CABG, p=0.06). For patients in the upper tercile - those with the most complex disease - there was a significant increase in MACCE for PCI patients as compared to CABG (28.2 percent as compared to 15.4 percent, p=0.001).

The SYNTAX Score is a novel angiographic tool used to measure the complexity of coronary artery disease based on nine anatomic criteria, including lesion frequency, complexity and location. Higher SYNTAX Scores indicate patients with more complex disease and increased treatment challenges. A SYNTAX Score website, www.syntaxscore.com, was launched in May and allows cardiologists and cardiac surgeons to characterize a patient's anatomical complexity, which can be used in combination with a physician's clinical judgment to help determine the best revascularization option.

The SYNTAX Score and SYNTAX Score website were developed under the direction of the SYNTAX trial steering committee, chaired by Patrick Serruys, M.D., Ph.D and F.W. Mohr, M.D., Ph.D., and were made possible by support from Boston Scientific and Cardialysis BV.

The safety and effectiveness of the TAXUS Express Stent System has not been established in patients with left main or three-vessel disease.

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.

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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