

Boston Scientific

SYNTAX Substudy Shows Positive Outcomes for Left Main Patients Treated With TAXUS® Express2® Stent System

PRNewswire

NATICK, Mass. and BARCELONA, Spain
(NYSE:BSX)

NATICK, Mass. and BARCELONA, Spain, May 19 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced positive outcomes from a substudy of patients with left main coronary disease who were treated with the TAXUS® Express2® Paclitaxel-Eluting Coronary Stent System. SYNTAX-LE MANS is a substudy of the landmark SYNTAX trial, the first randomized, controlled clinical trial to compare percutaneous coronary intervention (PCI) using the TAXUS Stent to coronary artery bypass graft (CABG) surgery in patients with left main disease and/or significant narrowing of all three coronary arteries (three-vessel disease). The substudy data were presented by A. Pieter Kappetein, M.D., Ph.D., at the annual EuroPCR Scientific Program in Barcelona.

SYNTAX-LE MANS compares late angiographic and clinical outcomes in 263 patients with left main disease (149 treated with the TAXUS Stent and 114 treated with CABG). It is designed to assess 15-month patency (vessel openness) and the safety of stents and grafts in this high-risk population; it includes separate primary endpoints for each treatment arm. For PCI patients, the primary endpoint is the rate of long-term patency (defined here as <50% stenosis) of the treated lesion sites. For CABG patients, the primary endpoint is the ratio of obstructed/occluded grafts (defined here as greater than or equal to 50% stenosis) to total placed grafts. Results were presented separately for each group, and no formal statistical inferences between the two groups were made due to the different primary endpoints. Results were also broken out by left main lesion location, including distal and non-distal.

For those patients receiving a TAXUS Stent, the patency rate for the treated lesion was 92 percent. Restenosis was more common with distal lesions (90% patency) compared with non-distal lesions (98% patency). Reported in-stent late loss was low at 0.2 mm for non-distal lesions. The reported 15-month MACCE rate (all-cause death, stroke, myocardial infarction and revascularization) for the TAXUS Stent patients was 13 percent, driven primarily by a nine percent repeat revascularization rate.

For CABG patients, the overall obstruction/occlusion ratio at 15 months was 16 percent, with six percent of grafts obstructed in the range of greater than or equal to 50% to <100%, and 10 percent of grafts occluded 100%. On a per patient basis, the obstruction/occlusion ratio was 27 percent, with nine percent of patients having a graft obstructed in the greater than or equal to 50% to <100% range and 18 percent of patients having a graft occluded 100%. The reported MACCE rate for CABG patients at 15 months was nine percent.

"The data announced today from SYNTAX-LE MANS will offer important insights for doctors as they evaluate treatment options for challenging left main patients," said Keith Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "We are encouraged by the high stent patency rate at 15 months, which increases our confidence in the application of PCI in this high-risk population. The results support previously announced outcomes with PCI and CABG in patients with left main disease."

The safety and effectiveness of the TAXUS Express2 Stent System have 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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