Boston Scientific

SYNTAX Analysis Finds Treatment With TAXUS® Express2® Stent System More Cost Effective Than Bypass Surgery in Patients With Complex Coronary Artery Disease

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NATICK, Mass. and BARCELONA, Spain, May 20 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of economic and quality of life outcomes, based on one-year data from its landmark SYNTAX trial. The results found that percutaneous coronary intervention (PCI) using the TAXUS® Express2® Paclitaxel-Eluting Coronary Stent System was consistently associated with fewer patient hospital days during the first year after treatment compared to coronary artery bypass graft (CABG) surgery. Total medical costs at one year were also lower with PCI. Analysis of the data was presented by Ben van Hout, Ph.D., of the University of Utrecht, The Netherlands, at the annual EuroPCR Scientific Program in Barcelona.

"This analysis demonstrates that although hospitalization patterns vary by country, PCI patients consistently benefit from shorter hospital stays during the first year following treatment, as compared to CABG patients," said Dr. van Hout. "This analysis will be especially helpful to physicians and hospital administrators as they consider the most cost-effective course of treatment for these complex patients."

"Today's findings reinforce previously announced results on economic and quality of life data from the SYNTAX trial," said Keith D. Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "The data show that PCI benefits patients and the health care system overall with shorter hospital stays, increased quality adjusted life years and lower total costs. When coupled with safety and efficacy data from the larger SYNTAX data set, this analysis supports PCI as a cost-effective treatment option for these challenging patients."

The SYNTAX economic analysis compared quality of life outcomes using standardized health outcome measures(1) and resource utilization associated with PCI and CABG surgery in patients in 11 European countries and the U.S. who qualified for one or the other revascularization option. The results indicated a short-term benefit for PCI versus CABG surgery, with no significant difference at one year, but with a gain in quality adjusted life years (QALY) of 0.02 in favor of PCI.

The analysis also included a detailed calculation of total medical costs at one year for all patients treated in the U.K., the country with the largest cohort of patients. Total costs included the initial procedure, all hospitalizations, repeat procedures and medication. Although initial procedure costs were similar (4,201 pounds Sterling for PCI vs. 4,246 pounds Sterling for CABG), total medical costs for PCI were 25 percent lower than CABG at one year (8,295 pounds Sterling PCI vs. 11,101 pounds Sterling CABG, $p<0.001$). The lower medical costs coupled with the net improvement in quality of life resulted in PCI as the dominant treatment strategy at one year.

Results further showed that although the average length of hospital stay varied by country, CABG patients were hospitalized on average an additional 7.8 days compared to PCI patients (13.7 vs. 5.9 days, including pre- and post-procedure).

SYNTAX is the first randomized, controlled clinical trial to compare PCI using the TAXUS® Express2® Paclitaxel-Eluting Coronary Stent System to CABG surgery in patients with left main disease and/or significant narrowing of all three coronary arteries (three-vessel disease). These complex patients are traditionally treated with CABG surgery and have been excluded from most prior drug-eluting stent clinical trials. The SYNTAX trial provides important data related to the treatment of these complex patients and should help physicians make more informed treatment decisions.

It has been previously reported that one-year SYNTAX data demonstrated comparable safety for the two treatment groups, with no overall statistically significant differences between PCI and CABG surgery in rates of death or myocardial infarction (MI, or heart attack), although there were more strokes in patients treated with CABG surgery. The rate of repeat revascularization was higher in the PCI group, although most procedures in the PCI group were repeat PCI, with only a small percentage requiring CABG surgery. However, because of the increased need for repeat procedures, the overall 12-month MACCE (Major Adverse Cardiovascular or Cerebrovascular Event rate, including all-cause death, stroke, MI and repeat revascularization) was higher for PCI.

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.

(1) The measure used was the EuroQoL EQ-5D, which assesses patient mobility, self care, usual activities, pain/discomfort and anxiety/depression.

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