Boston Scientific

# New England Journal of Medicine Publishes Results from Boston Scientific's Landmark SYNTAX™ Trial

PRNewswire
NATICK, Mass.
(NYSE:BSX)

**Data show comparable safety for complex patients treated with TAXUS® Express2™ Stents and bypass surgery**

NATICK, Mass., Feb. 18 /PRNewswire-FirstCall/ -- Boston Scientific Corporation today welcomed the publication of results from its landmark SYNTAX™ trial in this week's issue of the New England Journal of Medicine. In the study, percutaneous coronary intervention (PCI) using the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System was compared to contemporary coronary artery bypass graft (CABG) surgery in patients with the most complex coronary artery disease (CAD). Trial results at 12 months demonstrated no overall statistically significant differences between PCI and CABG in rates of death or myocardial infarction (heart attack), although PCI patients were more likely to require a repeat revascularization (mostly additional PCI) than were CABG patients.

The SYNTAX trial is the first randomized, controlled clinical trial to compare these two treatments 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 drug-eluting stent (DES) clinical trials.

"SYNTAX has provided the medical community with critical information on the management of patients with advanced and complex CAD," said Ted Feldman, M.D., F.S.C.A.I., Director of the Cardiac Catheterization Laboratory at NorthShore University HealthSystem in Evanston, Illinois, and a lead investigator of the trial. "While CABG may still be the preferred treatment in many patients with complicated disease, some patients may now be candidates for the less-invasive alternative offered by stents. These data will assist cardiologists in making treatment therapy decisions for these patients."

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 strategies (PCI or CABG). If either the cardiologist or surgeon felt that one revascularization technique was the preferred treatment, then patients were not randomized, but were entered into the corresponding registry. Accordingly, patients in the PCI registry had been rejected for cardiac surgery, and patients in the CABG registry had been rejected for PCI.

The patients recruited in the SYNTAX trial are a unique study group in the PCI field, given their exceptionally complex anatomy and advanced disease. The average PCI-treated patient enrolled in SYNTAX received 4.6 stents. By contrast, the average number of stents implanted in a PCI patient in everyday practice is 1.5. Further evidence of the complex nature of PCI-treated patients enrolled in SYNTAX include 33 percent of patients with >100 millimeters stented length, 72 percent with bifurcations, 22 percent with total occlusions and 39 percent with left main disease.

The final one-year results published today showed similar safety for the two randomized groups, with a combined rate of all-cause death, stroke and myocardial infarction (MI) of 7.6 percent for PCI and 7.7 percent for CABG (p=0.98). The rate of stroke itself was significantly lower for PCI (0.6 percent for PCI as compared to 2.2 percent for CABG, p=0.003). Overall 12-month MACCE (all-cause death, stroke, MI and repeat revascularization), however, was significantly higher for PCI (17.8 percent versus 12.4 percent, p=0.002), due to more repeat revascularization in the PCI arm (13.5 percent versus 5.9 percent, p=0.001). Most repeat revascularizations in the PCI arm, however, were performed by additional PCI, with only 2.8 percent of PCI patients ultimately requiring CABG.

"Boston Scientific is proud to sponsor the SYNTAX trial, and we are pleased that our robust DES clinical trial program is providing physicians with additional data to determine optimal treatment strategies for patients with challenging coronary artery disease," said Keith Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific.

The SYNTAX trial broke new ground by scientifically defining a new measure for anatomical complexity -- the SYNTAX™ Score™ -- which characterizes vasculature based on lesion number, complexity and location. In fact, PCI patients in the lower one-third of raw SYNTAX Score results had similar 12-month combined MACCE rates to

CABG patients (13.6 percent for PCI and 14.7 percent for CABG, p=0.71).

The TAXUS Express2 Paclitaxel-Eluting Coronary Stent System used in the SYNTAX trial has now been replaced by the Company's second-generation TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System, which has been approved for use in the United States, Europe and Japan. This stent represents Boston Scientific's latest advance in drug-eluting stent technology, with substantially thinner struts and a more flexible cell geometry for improved deliverability, as well as uniform strut distribution designed specifically for drug elution.

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 new product development and performance, clinical trials, regulatory approvals, alternative therapies and our growth strategy. 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.

CONTACTS: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

Web site: http://www.bostonscientific.com/

---