Boston Scientific

Landmark SYNTAX Trial Reports Comparable Safety Outcomes for Complex Patients Treated With TAXUS® Express2™ Stents or Bypass Surgery

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NATICK, Mass. and MUNICH, Germany
(NYSE:BSX)

NATICK, Mass. and MUNICH, Germany, Sept. 1 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced one-year 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 overall results demonstrated no statistically significant differences between PCI and CABG in rates of death or myocardial infarction (MI). The Company made the announcement at the annual European Society of Cardiology meeting in Munich, Germany.

The SYNTAX trial is the first randomized, controlled clinical trial to compare 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 on appropriate treatment options for the sickest patients.

"For PCI patients to do so well with such complex anatomy and advanced disease is extraordinary," said Keith Dawkins, M.D., Associate Chief Medical Officer of Boston Scientific. "These patients, the majority of whom are normally treated with surgery, are the most challenging group ever studied in a DES clinical trial."

The SYNTAX trial also demonstrated a significant decrease in the rate of stroke for patients treated with PCI as compared to CABG.

"The significant difference in the stroke rate between the PCI and the CABG groups is an important finding," said Dr. Dawkins. "Physicians and their patients will now have the necessary information to weigh the risk of stroke associated with CABG versus the known higher rate of revascularization with PCI. We were also surprised to find that the rate of symptomatic graft occlusion in the CABG group was equivalent to the rate of stent thrombosis in the PCI group."

The patients recruited in SYNTAX are a unique study group in the PCI field, given their exceptionally complex anatomy and advanced disease. The average SYNTAX 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 patient profile includes 33 percent of patients with >100 mm stented length, 84 percent with bi/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 results announced today showed comparable safety for the two treatment groups, with a combined rate of all-cause death, stroke and MI of 7.6 percent for PCI and 7.7 percent for CABG (p=0.98). The rate of stroke itself was 0.6 percent for PCI as compared to 2.2 percent for CABG (p=0.003). Overall 12- month MACCE (Major Adverse Cardiovascular or Cerebrovascular Event rate, including all-cause death, stroke, MI and repeat revascularization) was significantly higher for PCI (17.8 percent compared to 12.1 percent for CABG, p=0.0015).

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.

SYNTAX is breaking new ground by scientifically defining a new measure for anatomical complexity - the SYNTAX Score - which seeks to provide guidance to physicians on optimal treatment options for this high-risk group of patients. The SYNTAX Score characterizes vasculature based on lesion frequency, complexity and location, relying on data from the SYNTAX trial as well as information collected through other sources.

The safety and effectiveness of the TAXUS Express2 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: 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.

CONTACT: 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

On site at ESC in Munich

Natacha Gassenbach
(508) 250-9348 (mobile)
Media Relations
Boston Scientific

Geraldine Varoqui
(49) 170-782-85-58 (mobile)
Media Relations
Boston Scientific

SOURCE: Boston Scientific Corporation

CONTACT: Paul Donovan, Media Relations, +1-508-650-8541, +1-508-667-5165 (mobile), Larry Neumann, Investor Relations, +1-508-650-8696, both of Boston Scientific Corporation; or On site at ESC in Munich, Natacha Gassenbach, +1-508-250-9348 (mobile), Geraldine Varoqui, 49-170-782-85-58(mobile), both Media Relations of Boston Scientific

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