Boston Scientific

TAXUS® Express® Stent Shows Similarly Low Re-Intervention Rates in Patients With Diabetes Compared to Non-Diabetics in Arrive Registry Program

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NATICK, Mass. and WASHINGTON
(NYSE:BSX)

NATICK, Mass. and WASHINGTON, Oct. 12 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of nearly 7,500 patients from its TAXUS ARRIVE 1 and 2 registries, which are designed to confirm the performance of the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System in real-world practice. The two-year pooled ARRIVE data showed that the TAXUS Stent reduced clinical restenosis in patients with diabetes as effectively as in patients without diabetes, with no incremental risk of myocardial infarction (MI) or stent thrombosis. Analysis of the data was presented by John M. Lasala, M.D., Ph.D., F.A.C.C., at the Cardiovascular Research Foundation's (CRF) annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

"The ARRIVE diabetic subset data demonstrated that the TAXUS Stent mitigated the adverse effect of diabetes as a risk factor for restenosis and repeat procedures in the patients studied," said Dr. Lasala, Professor of Medicine, Washington University School of Medicine in St. Louis. "While the diabetic patients had more cardiac risk factors, comorbidity and higher mortality than non-diabetics, the rates of reintervention, MI and stent thrombosis in the ARRIVE 1 and 2 registries were similar in both groups, regardless of risk profile."

The pooled analysis included two-year data on 2,112 medication-requiring diabetic patients and 5,380 non-diabetic patients from the ARRIVE registry program. The population was further segmented into a higher-risk group(1) and a lower-risk group. Due to a significant increase in comorbid risk factors in patients with diabetes compared to non-diabetics, multivariate modeling and analysis was used to allow for adjustment of baseline differences (other than the presence of diabetes) between the two groups. Multivariate analysis was also used to determine predictors of target lesion revascularization (TLR) and mortality.

In the pooled ARRIVE 1 and 2 registry analysis, the TAXUS Stent maintained comparable re-intervention rates in the diabetic and non-diabetic patient populations. Cumulative two-year TLR rates, whether adjusted (7.1% vs. 6.8%, p=0.41) or unadjusted (8.2% vs. 7.7%, p=0.59), were similar between diabetic and non-diabetic patients, respectively. Diabetic patients in the higher-risk subgroup actually had lower adjusted TLR rates than non-diabetic patients (7.2% vs. 8.6%, p=0.03). Analysis of multivariate predictors showed that diabetes is not a significant predictor of TLR at two years in patients treated with the TAXUS Stent.

Safety outcomes at two years showed that diabetic patients treated with the TAXUS Stent in the ARRIVE registry had similar rates of MI (3.1% vs. 2.5%, p=0.35, adjusted) and ARC definite/probable stent thrombosis (2.3% vs. 1.9%, p=0.34, adjusted) compared to non-diabetic patients, whether or not multivariate adjustment was used. The results also showed that diabetic patients had the expected increase in two-year mortality compared to patients without diabetes (7.0% vs. 3.9%, p<0.001, adjusted), as well as increased cardiac death (4.3% vs. 2.1%, p<0.001), reflecting the more advanced cardiac disease and increased comorbid risk factors associated with diabetes. While diabetes was shown to be an independent predictor of mortality at two years in the overall study sample, the strongest predictors of two-year mortality in both the overall sample and in diabetic patients were renal disease, treated left main disease and congestive heart failure.

"Our extensive ARRIVE registries provide valuable insights into the benefits of the TAXUS Stent in treating diabetic patients who are often at higher risk for adverse events and repeat stenting procedures," said Donald S. Baim, M.D., Chief Medical and Scientific Officer at Boston Scientific. "The ARRIVE data demonstrated that the TAXUS Stent lessened the risk factor for clinical restenosis in the diabetic patients studied."

The growing diabetic subset accounts for more than one-quarter of all coronary interventional procedures in the United States. Diabetes is generally associated with an increased risk of overall mortality and cardiovascular events. In addition, patients with diabetes are more likely than non-diabetic patients to require repeat procedures due to a higher incidence of restenosis following angioplasty and stenting.

In the United States, the TAXUS Stent is not specifically indicated for use in patients with diabetes.

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/.

(1) The higher-risk group includes the following patient and lesion characteristics: vein graft, left main, bifurcation, severe calcification, cardiogenic shock, direct stenting of total occlusion, thrombus, severely tortuous vessels, total stent length >64mm, which are outside approved indications. The lower-risk group excludes these patient and lesion characteristics. Indications, contraindications, warnings, precautions and instructions for use can be found in the product labeling supplied with each device.

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, product performance and our market position. 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

SOURCE: Boston Scientific Corporation

CONTACT: Paul Donovan, Media Relations, +1-508-650-8541 (office), +1-508-667-5165 (mobile), or Larry Neumann, Investor Relations, +1-508-650-8696 (office), both of Boston Scientific Corporation

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

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