Boston Scientific

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

NATICK, Mass. and BARCELONA, Spain, May 13 /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 had similarly low rates of myocardial infarction (MI), stent thrombosis, and target vessel re-intervention (TVR) across both diabetic and non-diabetic patients. Analysis of the data was presented by David A. Cox, M.D., F.A.C.C., and John M. Lasala, M.D., Ph.D., F.A.C.C., at the annual EuroPCR Scientific Program in Barcelona.

"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. Cox of Lehigh Valley Hospital in Allentown, Pennsylvania. "While the diabetic patients had more cardiac risk factors, comorbidities and higher mortality than non-diabetics, the rates of re-intervention, 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(2). Due to significant disparity in baseline characteristics between diabetic and non-diabetic patients, multivariate modeling and analysis was used to allow for adjustment of baseline differences (other than the presence of diabetes) between the two groups.

In the ARRIVE registry analysis, the TAXUS Stent maintained comparable re-intervention rates in the diabetic and non-diabetic patient populations in ARRIVE 1 and 2. Cumulative two-year TVR rates, whether adjusted or unadjusted, were similar between diabetic and non-diabetic patients, respectively (9.8% vs. 9.0%, p=0.57, adjusted). Diabetic patients in the higher-risk subgroup actually had lower adjusted TVR rates than non-diabetic patients (9.5% vs. 11.3%, p=0.01). TAXUS Stent-related re-intervention of a target vessel (equivalent to target lesion revascularization, or TLR) was also similar between the patient groups (7.1% vs. 6.8%, p=0.31), despite the known higher risk for re-intervention in diabetic patients. In the higher-risk subgroup, two-year TLR was actually lower in diabetic patients after adjustment for baseline differences (7.3% vs. 8.7%, p=0.03).

Safety outcomes showed that diabetic patients treated with the TAXUS Stent in the ARRIVE registry had similar rates of MI (3.2% vs. 2.6%, p=0.29) and ARC Definite/Probable stent thrombosis (2.3% vs. 1.9%, p=0.27) compared to non-diabetic patients. The similarities held in both the higher- and lower-risk diabetic populations whether or not multivariate adjustment was used. The results also showed that both higher- and lower-risk diabetic patients had the expected increased overall adjusted two-year mortality rate compared to patients without diabetes (7.1% vs. 3.9%, p<0.001), as well as increased cardiac death (4.4% vs. 2.1%, p<0.001), reflecting the more advanced cardiac disease and increased comorbid risk factors associated with diabetes.

"Our extensive ARRIVE registries provide valuable insights into diabetic patients who are often at higher risk for adverse events and repeat stenting procedures," said Paul LaViolette, Chief Operating 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 cardiovascular events and 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/.

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.

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

CONTACT: Charles Rudnick
508-650-8660 (office)
617-935-1789 (mobile)
Media Relations
Boston Scientific Corporation

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

SOURCE: Boston Scientific Corporation

CONTACT: Charles Rudnick, Media Relations, +1-508-650-8660, +1-617-935-1789 (mobile), or Larry Neumann, Investor Relations, +1-508-650-8696, both of Boston Scientific Corporation

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

---

https://news.bostonscientific.com/stent-reintervention-rates-diabetes