Boston Scientific

TAXUS® Express™ Stent Shows Similarly Low Re-intervention Rates in Diabetic Patients Compared to Non-Diabetics in ARRIVE 1 and 2 registries

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NATICK, Mass. and CHICAGO, March 29 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of 4,772 patients from its TAXUS ARRIVE 1 and 2 registries, designed to assess the performance of the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System in real-world practice. The one-year pooled ARRIVE data confirmed the known higher mortality rate for diabetics versus non-diabetics with cardiovascular disease(1), but showed that the TAXUS Stent had similarly low rates of stent-related cardiac death, myocardial infarction (MI), stent thrombosis, and major cardiac events (MCE) across those two patient subsets. The study also showed similar rates of target vessel re-intervention (TVR) and TAXUS-related TVR in indicated patients(2) per the European Union (EU) label, whether or not they had diabetes. Analysis of the data was presented by D. Lynn Morris, M.D., at the SCAI Annual Scientific Sessions in Partnership with the ACC/i2 Summit in Chicago.

The pooled analysis included one-year data on 1,530 medication-requiring diabetic patients and 3,242 non-diabetic patients from the ARRIVE registry program. Due to significant disparity in baseline characteristics between diabetic and non-diabetic patients, propensity score analysis was used to allow for adjustment of baseline differences (other than the presence of diabetes) between the two groups.

The results showed diabetic patients had the well-known higher overall adjusted one-year mortality rate than patients without diabetes (3.7% vs. 2.3%, respectively, p=0.016), with the difference being driven by the cardiac death rate (2.3% vs. 1.2%, p=0.014), and reflecting the more advanced cardiac disease associated with diabetes. However, this difference was not related to the TAXUS Stent as the TAXUS Stent-related cardiac death rates at one-year were comparable in diabetics and non-diabetics, respectively (1.0% vs. 0.7%, p=0.29) in this patient population(2). Additionally, TAXUS Stent-related MCE rates (cardiac death, MI, and re-intervention) at one year were comparable (5.7% vs. 5.6%, p=0.80), as was the incidence of TAXUS Stent-related MI (1.6% vs. 1.2%, p=0.26), in both groups. Stent thrombosis at one year was low and showed no significant difference between diabetics and non-diabetics under Protocol definition (1.5% vs. 1.3%, p=0.59) or ARC Definite/Probable (1.7% vs. 1.2%, p=0.29). Unadjusted one-year rates of TAXUS Stent-related cardiac death, TAXUS Stent-related MCE, TAXUS Stent-related MI, and protocol-defined stent thrombosis showed no differences between the two populations (p-values of 0.30, 0.74, 0.31, and 0.65, respectively), suggesting that the safety profile is comparable for the two groups despite increased underlying risk in patients with diabetes.

Additionally, the ARRIVE analysis confirmed that the TAXUS Stent maintained comparable re-intervention rates in the diabetic and non-diabetic patient populations in ARRIVE 1 and 2. Rates of one-year TVR, whether adjusted or unadjusted, were similar between the patient groups (6.1% vs. 6.0%, p=0.80, adjusted). TAXUS Stent-related re-intervention of a target vessel (equivalent to target lesion revascularization, or TLR) was also similar between the patient groups (4.3% vs. 4.5%, p=0.70), despite the known higher risk for re-intervention in diabetic patients.

"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. Morris of the Albert Einstein Medical Center in Philadelphia, PA. "While the diabetic patients had more cardiac risk factors and co-morbidities than non-diabetics, the TAXUS- related cardiac death, MI and stent thrombosis in the ARRIVE 1 and 2 registries were similar in both groups, even without adjustment for risk factors."

"Our extensive ARRIVE registries provide valuable insights into diabetic patients who are often at higher risk for mortality and repeat stenting procedures," said Paul LaViolette, Chief Operating Officer at Boston Scientific. "The ARRIVE data demonstrated that the TAXUS Stent neutralized diabetes as a risk factor for clinical restenosis in the 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.

The safety and effectiveness of the TAXUS Express Stent has not been established in patients with diabetes in the United States.

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.

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(1) Rosamond W, Flegal K, Furie K, et al., ''Heart disease and stroke statistics--2008 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee.'' Circulation. 2008; 117(4):e25-146.

(2) Excludes the following patient and lesion characteristics that are off-label in the EU: vein graft, left main, bifurcation, severe calcification, direct stenting of total occlusion, thrombus, severely tortuous vessels, total stent length >64mm.

SOURCE: Boston Scientific Corporation

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