Boston Scientific

Real-World Data from ARRIVE Registries Show Favorable Outcomes for TAXUS® Express™ Stent

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NATICK, Mass. and CHICAGO, March 29 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of two-year data from more than 7,000 patients in the TAXUS ARRIVE Registry program. The study was designed to evaluate the safety performance of the TAXUS® Express2™ Paclitaxel-Eluting Coronary Stent System in patients treated in "real-world" practice. Outcomes through two years in the simple- use (single vessel/stent) patient group confirmed the favorable results seen in similar patients enrolled in previous TAXUS randomized clinical trials (the clinical trial cohort). Results in the more complex expanded-use group also continued the expected slightly higher event rates than simple-use patients, but were still favorable through two years compared to the published outcomes of other treatment modalities for such patients. Analysis of the data was presented by John M. Lasala, M.D., Ph.D., at the SCAI Annual Scientific Sessions in Partnership with the ACC/i2 Summit in Chicago.

"The extensive ARRIVE data show favorable and consistent outcomes in high- risk groups representing some of the most complex patients and lesions," said Dr. Lasala, Professor of Medicine, Washington University School of Medicine in St. Louis. "Outcomes in the simple-use patients in ARRIVE are consistent with results from the TAXUS Stent cohorts in the TAXUS randomized clinical trial program, indicating that the ARRIVE methodology is very efficient in capturing adverse event outcomes. Overall, then, these results support the long-term performance of the TAXUS Stent across the broad range of patients studied in these trials and registries."

The pooled analysis included two-year outcomes for 7,033 patients in the ARRIVE 1 and 2 registries, including those with long lesions, bifurcations, graft stenting, significant calcifications, and multi-vessel stenting. There were no differences in two-year safety rates (all death, Q-wave myocardial infarction (MI), or ARC definite/probable stent thrombosis) between ARRIVE simple-use patients and the clinical trial cohort. Adverse event rates at one year were expectedly higher for expanded-use versus simple-use ARRIVE patients, and included all death (4.2% vs. 2.3%, respectively), all MI (1.8% vs. 1.2%), target lesion revascularization (TLR) (6.2% vs. 3.4%), and ARC stent thrombosis (2.2% vs. 0.9%). However, TAXUS Stent-related adverse event rates during the second year of follow-up were lower for both expanded-use and simple-use patients than in the first year. Overall rates for TAXUS Stent- related events in ARRIVE were within expected ranges given the patient complexity.

Through two years, medically treated diabetic patients had a higher rate of all death (9.7% vs. 5.1%, $p<0.0001$) compared to non-diabetic patients but similar rates of TLR (8.1% vs. 7.7%, $p=0.63$), MI (2.5% vs. 2.2%, $p=0.40$), and ARC stent thrombosis (3.0% vs. 2.4%, $p=0.13$). Patients with graft stenting or stenting of bifurcation lesions had significantly higher rates of ARC stent thrombosis and TLR through two years, as expected given the complexity of the lesions treated.

"Our ARRIVE registry data provide valuable insights into the benefits of the TAXUS Stent in treating the broad spectrum of disease seen in real-world interventional practice," said Paul LaViolette, Chief Operating Officer at Boston Scientific. "The analysis reinforces data observed in our randomized clinical trials, showing positive long-term performance of the TAXUS Stent."

The safety and effectiveness of the TAXUS Express Stent has not been established in lesions longer than 28mm, bifurcations, saphenous vein grafts, multi-vessel stenting or diabetics.

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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