Boston Scientific

# ARRIVE Registry Analysis Demonstrates Continued Safety and Efficacy of TAXUS® Stent in Complex Real-World Patients

NATICK, Mass. and WASHINGTON, Oct. 21 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of nearly 7,000 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 pooled ARRIVE data showed continued low incidences of adverse events and repeat revascularization through two years in complex patients treated with the TAXUS Express2 Stent. Analysis of the data was presented at the Cardiovascular Research Foundation's (CRF) nineteenth annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

The ARRIVE registries enrolled 7,307 patients across the United States, including high-risk patients with complex lesions considered part of expanded use subgroups(i)(64 percent). The analysis included two-year data on 2,319 patients from ARRIVE 1 and one-year data on a pooled group of 6,979 patients from ARRIVE 1 and 2. The objective of the analysis was to determine if the safety and efficacy of the TAXUS Express2 Stent System demonstrated in simpler randomized clinical trials would translate to more complex populations treated in routine clinical practice.

One-year results from the 6,979 patients in the pooled data set showed event rates 3.5% for all death, 0.6% for Q-wave MI (myocardial infarction), and 5.1% for TAXUS-related target vessel revascularization (TVR, or re-treatment rate). Stent thrombosis per ARC definition definite plus probable in the pooled patient set was 1.7%. As expected, these safety outcomes at one year represent higher rates given the patient and lesion risk profiles and are in line with findings from previous studies.

Event rates from the 2,487 patients in ARRIVE 1 showed improvement from year one to year two with lower rates of all death (2.2%, 5.7% cumulative), Q-wave MI (0.3%, 0.9% cumulative), TAXUS-related TVR (2.5%, 7.6% cumulative) and ARC defined stent thrombosis (0.8%, 2.5% cumulative). The two-year event rates for expanded use patients were comparable to the simpler (TAXUS IV-like) patients with single stent lesions, including ARC stent thrombosis which was equivalent for complex and simple lesion patients at 0.8%.

In the medication-requiring diabetic sub-population (2,054 patients), diabetics had higher rates of death at two years compared to non-diabetics (8.3% vs. 4.6%) but no increase in TAXUS-related TVR (7.6% for both groups). The cumulative rates of Q-wave MI at two years were 0.6% for diabetic patients and 1.0% for non-diabetics. Two-year ARC defined stent thrombosis was 3.2% for diabetics and 2.3% for non-diabetics.

"ARRIVE represents the largest reported series of drug-eluting stent patients in selected high-risk subgroups," said John M. Lasala, M.D., PhD, Professor of Medicine, Washington University School of Medicine. "Considering the complexity of patients studied, the ARRIVE data indicate acceptable TAXUS- related incidence rates observed at one year and favorable safety and performance at two years. The data show consistent outcomes in high-risk patient groups representing a broad spectrum of procedural complexity seen in real-world practice."

"Our extensive ARRIVE registries provide valuable insight into the benefits of the TAXUS Stent in real-world drug-eluting stent use," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "The results are helpful in identifying low frequency TAXUS stent-related events and provide information on expanded use in complex patient populations."

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, product performance and competitive offerings. 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.

(i) Complex subgroups included patients presenting with acute myocardial infarction, diabetes, multi-vessel disease, small vessels (<2.5mm), or long lesions (>28mm). Complex patients had at least one of the following lesion types: in-stent restenosis, left main, graft stenting, chronic total occlusion, bifurcation lesion, ostial lesion, lesion length >28mm, multi-vessel stenting, moderate to severe calcification, severe tortuosity, vessel size <2.5mm, and failed brachytherapy. The safety and efficacy of the TAXUS Express2 stent system have not been established in these patient populations or in patients with diabetes.

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