Boston Scientific

Taxus Atlas Studies Reinforce Safety and Efficacy of Boston Scientific's Next-Generation Taxus Liberte Stent

NATICK, Mass., and WASHINGTON, Oct. 12 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced comprehensive data from the TAXUS ATLAS clinical program, a series of global, prospective, multi-center, single-arm, historically controlled trials, which evaluate the TAXUS® Liberte® Paclitaxel-Eluting Stent System in a variety of lesions and patient groups. The TAXUS Liberte Stent received U.S. Food and Drug Administration approval on Friday. Results from the TAXUS ATLAS Workhorse, Direct Stenting, Small Vessel and Long Lesion trials were presented at the Cardiovascular Research Foundation's (CRF) annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

"The TAXUS ATLAS studies reinforce the long-term safety and efficacy of the TAXUS Liberte Stent while demonstrating the ability to access complex lesions. The data showed significantly reduced restenosis in small vessels and positive results in direct stenting procedures," said Mark A. Turco, M.D., Director of the Center for Cardiac and Vascular Research, Washington Adventist Hospital, and co-principal investigator of the trial. "The positive ATLAS data suggest that improvements in stent design and a reduction in strut thickness may contribute to improved clinical outcomes for patients treated with the TAXUS Liberte Stent."

TAXUS ATLAS Workhorse

Three-year data from the TAXUS ATLAS Workhorse study were presented by Dr. Turco. TAXUS ATLAS Workhorse enrolled 871 patients at 61 sites, comparing patients with de novo coronary lesions treated with the TAXUS Liberte Stent to a historical case-matched TAXUS Express™ Stent control group.

In spite of more complex patients treated with the TAXUS Liberte Stent, the adjusted data demonstrated that the safety and efficacy benefits of the TAXUS Liberte Stent System were maintained at three years in workhorse lesions. The study reported similar rates of target lesion revascularization (TLR) of 9.3 percent for the TAXUS Liberte Stent vs. 9.6 percent for the TAXUS Express control stent (p=0.81). Three-year data also showed comparable rates of cardiac death (3.4 percent for the TAXUS Liberte Stent vs. 2.3 percent for the TAXUS Express Stent, p=0.20) and overall myocardial infarction (MI) (5.2 percent for the TAXUS Liberte Stent vs. 6.3 percent for the TAXUS Express Stent, p=0.36). The adjusted rate of ARC definite/probable stent thrombosis at three years for the TAXUS Liberte Stent group was 2.0 percent, as compared to 2.2 percent for the control group (p=0.76). Since the trial's primary end point was reported at nine months, the overall target vessel revascularization (TVR) rate through three years was significantly lower for the TAXUS Liberte Stent group (6.1 percent versus 9.1 percent for control, p=0.0178), suggesting a late benefit of the thin-strut TAXUS Liberte Stent.

TAXUS ATLAS Direct Stent

Dr. Turco also presented two-year data from the TAXUS ATLAS Direct Stent clinical trial, a 247-patient study assessing the safety of direct stenting with the TAXUS Liberte Stent compared to placement of a TAXUS Liberte Stent using balloon pre-dilatation. The control arm for the trial is the angiographic cohort of the TAXUS ATLAS Workhorse clinical trial, which mandated pre-dilatation. Although the ATLAS Workhorse and ATLAS Direct Stent trials had the same inclusion and exclusion criteria, simpler lesions were selected for the direct stent group.

The study reported a low two-year adjusted overall MACE (major adverse cardiac events) rate of 11.2 percent for the direct stent group, as compared to 19.1 percent for the pre-dilatation control group (p=0.0055). This difference was driven mainly by the 67 percent lower rate of target lesion revascularization (TLR) in the direct stent group (3.0 percent versus 9.0 percent, p=0.0005). The additional components of MACE (cardiac death and overall MI) were low and comparable between the two groups. The study also reported a significantly lower adjusted rate of ARC definite/probable stent thrombosis for the direct stent group at 0.3 percent, as compared to 2.1 percent for the control group (p=0.0113).

"Overall, the trial suggests that using the direct stenting method with the TAXUS Liberte Stent in carefully selected lesions can result in improved outcomes through two years compared with pre-dilatation," said Dr. Turco.

TAXUS Atlas Small Vessel and Long Lesion

Two-year data from the TAXUS ATLAS Small Vessel and Long Lesion studies were presented by John A. Ormiston, M.D., Green Lane and Mercy Hospital, Auckland, New Zealand and co-principal investigator of the trial. The TAXUS ATLAS Small Vessel study is designed to evaluate the long-term safety and efficacy of the TAXUS Liberte 2.25 mm Stent compared to the highly effective first-generation TAXUS Express™ 2.25 mm Stent.

The TAXUS Liberte 2.25 mm Stent showed a statistically significant reduction in target lesion revascularization (TLR) at two years with a rate of 8.2 percent as compared to 20.3 percent in the TAXUS Express Stent (p=0.0046), resulting in a 60 percent relative reduction. Overall target vessel revascularization (TVR) was 12.8 percent for the TAXUS Liberte Stent compared to

26.1 percent for the TAXUS Express Stent (p=0.0072), a 51 percent reduction. The two-year MACE rate for the TAXUS Liberte 2.25 mm Stent was 16.5 percent compared to 30.4 percent for the TAXUS Express Stent (p=0.0098), a relative reduction of 46 percent. ARC definite/probable total stent thrombosis at two years was 0.8 percent for the TAXUS Liberte 2.25 mm Stent compared to 1.5 percent for the TAXUS Express Stent control group (p=0.52).

"The TAXUS Liberte 2.25 mm Stent significantly reduced restenosis and maintained or improved safety outcomes in small vessels compared to the TAXUS Express Stent," said Dr. Ormiston.

The TAXUS ATLAS Long Lesion study is designed to assess the long-term safety and efficacy of the TAXUS Liberte Long (38 mm) Stent compared with the TAXUS Express Stent in patients with long lesions. Two-year data showed the TAXUS Liberte Long Stent maintained safety and effectiveness results in treating long lesions. TLR was 9.1 percent for the TAXUS Liberte Long Stent compared to 10.1 percent for the TAXUS Express Stent (p=0.76). The composite measure of cardiac death or MI showed a significant 63 percent reduction in TAXUS Liberte Long Stent patients compared to TAXUS Express Stent patients (3.5 percent vs. 9.4 percent, p=0.0426). All cause death was reported as 2.8 percent for the TAXUS Liberte Long Stent and 4.3 percent for the TAXUS Express Stent (p=0.53). The TAXUS Liberte Long Stent showed no stent thrombosis at two years using either the Protocol definition or the ARC definite/probable definition while the TAXUS Express control Stent reported 0.8 percent (p=0.49) using the Protocol definition and 1.5 percent (p=0.24) using the ARC definition.

"The next-generation TAXUS Liberte Stent, with its thinner struts and more uniform cell geometry, was able to reduce the risk of cardiac death or MI at two years for patients with long lesions in this study," added Dr. Ormiston.

The Company received the CE Mark for the TAXUS Liberte Stent in Europe and other international markets in September 2005, and received CE Mark for the TAXUS Liberte Long Stent in May 2007. The Company received U.S. Food and Drug Administration approval for its TAXUS Express2™ Atom™ Paclitaxel-Eluting Coronary Stent System for use in vessels as small as 2.25 mm in diameter and the TAXUS Liberte Stent for coronary vessels 2.5 mm to 4.0 mm in diameter. The TAXUS Liberte 2.25 mm Stent and the TAXUS Liberte Long Stent are currently pending approval by the U.S. Food and Drug Administration and are limited by federal law to investigational use and not available for sale 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, 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.

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