

Boston Scientific's Next-Generation Stent Shows Improved Clinical Outcomes in Complex Lesions

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(NYSE:BSX)

NATICK, Mass. and WASHINGTON, Oct. 22 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced nine-month data from the pivotal TAXUS ATLAS Small Vessel and Long Lesion studies, which evaluate the TAXUS® Liberte® Paclitaxel-Eluting Stent System in complex lesions. The TAXUS Liberte 2.25 mm Stent significantly reduced restenosis and maintained or improved safety outcomes compared to the already highly effective first- generation TAXUS Express™ Stent, which has been used in more than four million implants since 2003 and has been the benchmark against which many newer stents have been compared. The TAXUS Liberte Long (38 mm) Stent showed further significant reduction in the incidence of Non-Q-Wave Myocardial Infarction (MI, or heart attack) occurring at the time of the procedure compared to the earlier generation TAXUS stent. The data also demonstrated enhanced deliverability for both the TAXUS Liberte 2.25 mm Stent and for the TAXUS Liberte Long Stent.

The results were presented by Mark A. Turco, M.D., Director of the Center for Cardiac and Vascular Research, Washington Adventist Hospital, and co- principal investigator of the trial, at the Cardiovascular Research Foundation's (CRF) nineteenth annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

"The TAXUS ATLAS studies show the TAXUS Liberte Stent to be highly deliverable in complex lesions, while significantly reducing restenosis in small vessels," said Dr. Turco. "The positive data from the TAXUS ATLAS studies suggest that improvements in stent design and a reduction in strut thickness may contribute to improved clinical outcomes for TAXUS Liberte in these difficult and challenging lesions."

"Results from the TAXUS ATLAS studies demonstrate the successful transfer of Boston Scientific's leading paclitaxel technology to our next-generation TAXUS Liberte Stent," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "Improved clinical outcomes and positive data on deliverability in complex lesions are a powerful demonstration of the continued leadership of Boston Scientific and our TAXUS Stent platform. TAXUS Liberte is the preferred drug-eluting stent in virtually every country where it is sold, and we look forward to bringing this technology to the U.S. in 2008."

The TAXUS ATLAS Small Vessel and Long Lesion studies are global, multi- center, historically controlled trials investigating de novo lesions in 411 patients at 24 sites. The Small Vessel study was designed to evaluate the safety and efficacy of the TAXUS Liberte 2.25 mm Stent for superiority compared to a case-matched historical bare-metal stent (BMS) control (Express Stent), and non-inferiority against a case-matched historical control of TAXUS Express Stent patients. The Long Lesion study was designed to demonstrate that the TAXUS Liberte Long (38 mm) Stent is non-inferior in safety and efficacy compared to a case-matched historical control of TAXUS Express Stent patients.

The Small Vessel study met its primary superiority endpoint compared to the BMS group (45.6% vs. 32.1% diameter stenosis, $p < 0.0001$) and non- inferiority compared to the TAXUS Express group (38.4% vs. 32.1% diameter stenosis, $p = 0.0351$). The TAXUS Liberte 2.25 mm Stent showed significant statistical reduction in target lesion revascularization (TLR) at nine months with a rate of 5.8% as compared to 13.7% in the TAXUS Express Stent ($p = 0.024$), resulting in a 58% relative reduction. Overall target vessel revascularization (TVR) was 10.1% for the TAXUS Liberte Stent compared to 17.8% for the TAXUS Express Stent ($p = 0.07$).

Major adverse cardiac events (MACE) for the TAXUS Liberte 2.25 mm Stent was 12.8% compared to 20.5% for the TAXUS Express Stent ($p = 0.10$), a relative reduction of 38%. All cause death was 1.2% for the TAXUS Liberte 2.25 mm Stent group and 2.7% for the TAXUS Express group ($p = 0.30$). ARC-defined total stent thrombosis to nine months was 0.4% for the TAXUS Liberte 2.25 mm Stent compared to 1.3% for the BMS control ($p = 0.56$) and 1.4% for the TAXUS Express Stent control group ($p = 0.39$).

The TAXUS Liberte Long (38mm) Stent met its primary endpoint of non- inferiority to the TAXUS Express control Stent in percent diameter stenosis (32.6% vs. 31.7%, $p = 0.71$). Overall TVR was 8.7% for the TAXUS Liberte Long Stent compared to 8.5% for the TAXUS Express Stent ($p = 0.93$). Enhanced deliverability was demonstrated through clinical procedural success, which favored the TAXUS Liberte Long Stent over the TAXUS Express Stent (100.0% vs. 96.3%, $p = 0.0431$).

Myocardial infarction (MI) was significantly reduced in TAXUS Liberte Long Stent patients compared to TAXUS Express patients (1.3% vs. 6.3%, $p = 0.026$). The reduction in MI was primarily driven by a decrease in in-hospital Non-Q-Wave MI in the TAXUS Liberte Stent group as compared to the TAXUS Express Stent group (0.0% vs. 4.1%, $p = 0.013$). The MI reduction in TAXUS Liberte Long patients was also reported in a cohort of single stent patients (1.6% vs. 9.1%, $p = 0.0213$).

All cause death was reported as 2.8% for the TAXUS Express Stent and 0.7% for the TAXUS Liberte Long Stent ($p = 0.21$). The

TAXUS Liberte Long Stent showed no stent thrombosis at 284 days using either the Protocol Definition or the ARC Definition while the TAXUS Express control Stent reported 0.7% (p=0.49) using the Protocol Definition and 1.4% (p=0.24) using the ARC Definition.

The Company received the CE Mark for the TAXUS Liberte Stent in Europe and other international markets in September 2005, and it is currently the market- leading drug-eluting stent outside the United States excluding Japan (the TAXUS Liberte stent is not available for sale in Japan). The Company received CE Mark for the TAXUS Liberte Long Stent in May 2007. The TAXUS Liberte Stent and the TAXUS Express 2.25 mm 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. The Company plans to launch the TAXUS Liberte Stent in the United States in 2008.

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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