

Long-Term Data Show Advantages for TAXUS® Liberte® Stent in Small Vessels and Long Lesions

NATICK, Mass., Sept. 22 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today announced comprehensive data from the TAXUS ATLAS clinical program, a series of global, prospective, single-arm trials evaluating the TAXUS® Liberte® Paclitaxel-Eluting Stent System in a variety of lesions and patient groups. Five-year results from the TAXUS ATLAS trial and four-year results from the TAXUS ATLAS Small Vessel and Long Lesion trials continue to show significant advantages for the thin-strut TAXUS Liberte Stent when compared to the first-generation TAXUS® Express® Stent. Analysis of the data was presented by the Co-Principal Investigators of the TAXUS ATLAS trials, Mark A. Turco, M.D., Director of the Center for Cardiac and Vascular Research, Washington Adventist Hospital, and John A. Ormiston, M.D., Mercy Angiography Unit, Mercy Hospital, Auckland, New Zealand, at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics scientific symposium in Washington, D.C.

"The TAXUS ATLAS trials continue to reinforce the long-term safety and efficacy of the TAXUS Liberte Stent in a variety of complex lesions," said Dr. Turco. "The data showed sustained positive outcomes in workhorse lesions, significantly reduced rates of re-intervention in small vessels and important safety differences in long lesions. The 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" Lesions

Data from 871 patients in the TAXUS ATLAS trial demonstrated that the durable safety and efficacy profile of the TAXUS Liberte Stent is maintained at five years in *de novo* coronary ("workhorse") lesions. In spite of more complex patients treated with the TAXUS Liberte Stent, the unadjusted data showed comparable clinical outcomes between the TAXUS Liberte Stent and a historical case-matched TAXUS Express® Stent control group. The study reported similar rates of target lesion revascularization (TLR) of 11.0 percent for the TAXUS Liberte Stent vs. 11.5 percent for the TAXUS Express Stent ($p=0.72$).

Five-year data also showed comparable rates of cardiac death (5.1 percent for the TAXUS Liberte Stent vs. 4.4 percent for the TAXUS Express Stent, $p=0.49$) and overall myocardial infarction (MI) (7.6 percent for the TAXUS Liberte Stent vs. 8.4 percent for the TAXUS Express Stent, $p=0.57$). The rate of ARC(1) definite/probable stent thrombosis at five years was 3.0 percent for the TAXUS Liberte Stent vs. 2.7 percent for the TAXUS Express Stent ($p=0.76$).

TAXUS Atlas Small Vessel

Four-year data were presented from the TAXUS ATLAS Small Vessel trial, which is designed to evaluate the long-term safety and efficacy of the TAXUS Liberte Atom™ (2.25 mm) Stent compared to lesion-matched patients from the TAXUS V trial treated with either 2.25 or 2.5 mm bare-metal Express® Stents or the TAXUS Express® 2.25 mm Stent. The TAXUS Liberte 2.25 mm Stent showed significantly lower rates of TLR (10.8 percent vs. 23.8 percent, $p=0.008$), target vessel revascularization (or TVR, 16.5 percent vs. 31.7 percent, $p=0.007$), target lesion failure (or TLF, 15.4 percent vs. 30.2 percent, $p=0.007$) and major adverse cardiac events (or MACE, 21.6 percent vs. 36.5 percent, $p=0.02$) sustained at four years compared with the TAXUS Express 2.25 mm Stent and similar significant reductions compared to the bare-metal Express Stent group. All stents showed comparable rates of total death, cardiac death, MI and ARC definite/probable stent thrombosis.

"The TAXUS Liberte 2.25 mm Stent significantly reduced restenosis and maintained safety outcomes in small vessels compared to the TAXUS Express 2.25 mm Stent and Express bare-metal stents," said Dr. Ormiston. "Since TAXUS Liberte uses the same drug/polymer coating as TAXUS Express, I believe these improved clinical outcomes in small vessels likely result from the thinner struts and improved stent geometry of the TAXUS Liberte Stent."

TAXUS Atlas Long Lesion

Four-year data were also presented from the TAXUS ATLAS Long Lesion trial, which is designed to assess the safety and efficacy of the TAXUS Liberte Long (38 mm) Stent in patients with long coronary lesions compared to a case-matched patient cohort from the TAXUS IV and V trials treated with TAXUS Express Stents. In a subgroup analysis of patients treated with a single stent, the TAXUS Liberte Long Stent showed significantly reduced rates of target-vessel MI (2.6 percent vs. 12.9 percent, $p=0.02$) and target-vessel non-Q-wave MI (2.6 percent vs. 11.3 percent, $p=0.03$) compared to the TAXUS Express Stent at four years. Both stent groups demonstrated comparable rates of TLR, MACE and ARC definite/probable stent thrombosis.

"The TAXUS Liberte Long Stent maintained a continued long-term safety benefit in patients with long lesions, resulting in lower target vessel-related MI and a numerically lower rate of cardiac death compared to the TAXUS Express Stent," said Dr. Turco.

About Boston Scientific

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: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 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 hereafter. 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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