Boston Scientific

Boston Scientific's TAXUS® Element™ Stent Demonstrates Strong Outcomes in Diabetic Patients

NATICK, Mass., Sept. 22 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an analysis of 1,166 patients from its PERSEUS clinical program comparing the performance of the TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System in diabetic versus non-diabetic patients. Results demonstrated that despite the known increased risk of restenosis for diabetics versus non-diabetics in patients undergoing coronary revascularization, the TAXUS Element Stent had comparable levels of target lesion revascularization (TLR) and late loss in both diabetic and non-diabetic patients. Analysis of the data was presented by Louis A. Cannon, M.D., of the Cardiac and Vascular Research Center of Northern Michigan in Petoskey, Michigan, and Co-Principal Investigator of the PERSEUS clinical program, at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics scientific symposium in Washington, D.C.

"The PERSEUS diabetic subset data showed that the TAXUS Element Stent mitigated the impact of diabetes as a risk factor for restenosis following stenting procedures in the patients studied," said Dr. Cannon. "At one year, no significant differences in measures of stent efficacy were observed between the two patient groups. Diabetic status was not a predictor of re-intervention in patients treated with the TAXUS Element Stent."

The PERSEUS diabetic analysis included clinical outcomes at one year among 314 diabetic patients and 852 non-diabetic patients treated with the TAXUS Element Stent from the PERSEUS Workhorse and Small Vessel clinical trials. Due to significant disparity in baseline characteristics between diabetic and non-diabetic patients, propensity score analysis was used to allow for adjustment of baseline differences (other than the presence of diabetes) between the two groups.

Results showed that the TAXUS Element Stent maintained comparable rates of TLR at one year, whether adjusted or unadjusted, in the diabetic and non-diabetic patient populations (5.5 percent vs. 4.1 percent, p=0.43, adjusted). The adjusted and unadjusted rates of target lesion failure (TLF) at one year (defined as ischemia-driven TLR, or MI/cardiac death related to the target vessel) were also similar between the patient groups (7.5 percent vs. 5.4 percent, p=0.31, adjusted). Adjusted one-year rates of MACE, cardiac death, MI and ARC(1) definite/probable stent thrombosis showed no differences between the two populations (p-values of 0.14, 0.12, 0.38, and 0.77, respectively).

Nine-month adjusted angiographic outcomes showed similar in-segment late loss in diabetics and non-diabetics (0.23 mm vs. 0.19 mm, p=0.52). Rates of late loss for the TAXUS Element Stent were numerically lower than rates in prior studies for the TAXUS Express® and TAXUS Liberte® Stents(2).

"The PERSEUS diabetic analysis reinforces the historically consistent performance of paclitaxel in diabetic patients compared to non-diabetic patients," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific's Cardiology, Rhythm and Vascular Group. "The paclitaxel-based TAXUS Element Stent has a unique mechanism of action that helps inhibit restenosis across a wide variety of patients with coronary artery disease."

The TAXUS Element Stent leverages the performance advantages of the Element platform with a decade of clinical success from the TAXUS program. The novel stent architecture and proprietary platinum chromium alloy combine to offer greater radial strength and flexibility. The stent architecture helps create consistent lesion coverage and drug distribution while improving deliverability, which is enhanced by an advanced catheter delivery system. The higher density alloy provides superior visibility and reduced recoil while permitting thinner struts compared to prior-generation stents(3).

"We are pleased to see the strong performance of the TAXUS Element Stent in both the overall population of the PERSEUS trial and the diabetic patient subset," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "As the worldwide prevalence of diabetes continues to increase dramatically, these findings are very encouraging for physicians and their patients."

Diabetes is generally associated with an increased risk of cardiovascular events and patients with diabetes are more likely than non-diabetic patients to require repeat procedures due to a higher incidence of restenosis following angioplasty and stenting.

In March, the Company announced one-year results from its PERSEUS clinical program demonstrating positive safety and efficacy outcomes for the TAXUS Element Stent System compared to prior-generation Boston Scientific stents in more than 1,486 patients in two parallel trials at 90 centers worldwide.

The TAXUS Element Paclitaxel-Eluting Stent System received CE Mark approval in May, which included a specific indication for the treatment of diabetic patients. The Company received CE Mark approval for the PROMUS® Element™ Everolimus-Eluting Stent System in October 2009. Both Element systems incorporate the same platinum chromium alloy, innovative stent design and advanced catheter delivery system.

The Company expects U.S. Food and Drug Administration approval for the TAXUS Element Stent System(4) in mid 2011 and

for the PROMUS Element Stent System in mid 2012. In Japan, the Company expects approval for the TAXUS Element Stent System in late 2011 or early 2012 and for the PROMUS Element Stent System in mid 2012.

In the U.S., the TAXUS Element (ION) Stent and the PROMUS Element Stent are investigational devices and are limited by applicable law to investigational use only and are not available for sale.

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, new product launches, 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 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.

(1) Academic Research Consortium

(2) The TAXUS Express and TAXUS Liberte Stent Systems are not specifically indicated for diabetic patients in the U.S.

(3) Based on bench testing. Data on file with Boston Scientific.

(4) The TAXUS Element Stent System will be commercialized as the ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System in the U.S.

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