Boston Scientific

TAXUS® Stent Demonstrates Similar Outcomes in Diabetic Patients Compared to Non-diabetics in Pooled Analysis of TAXUS IV and V Trials

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NATICK, Mass. and CHICAGO, April 1, 2008 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from a pooled analysis of patients from its TAXUS IV and TAXUS V randomized clinical trials. The analysis compared the safety and efficacy of the TAXUS® Express™ Paclitaxel-Eluting Coronary Stent System in diabetic versus non-diabetic patients. Results demonstrated that despite the known increased rates of mortality and restenosis for diabetics versus non-diabetics in patients with cardiovascular disease(1), the TAXUS Stent had comparable levels of late loss and target lesion revascularization (TLR) across these patient populations. The study also showed no significant differences in target vessel revascularization (TVR), stent thrombosis, or myocardial infarction (MI), after adjustments were made for differences in other baseline characteristics between patients with or without diabetes. Analysis of the data was presented by Gregg W. Stone, M.D., of the Columbia University Medical Center in New York, at the SCAI Annual Scientific Sessions in Partnership with the ACC/i2 Summit in Chicago.

"The TAXUS IV/V diabetic subset data indicated that the TAXUS Stent mitigated the impact of diabetes as a risk factor for restenosis following stenting procedures in the patients studied," said Dr. Stone. "Diabetic patients treated with TAXUS Stents compared to bare-metal stents had significantly improved event-free survival, particularly important in high-risk patients with diabetes."

The pooled analysis included angiographic outcomes at nine months and clinical outcomes at three years among 338 diabetic patients and 901 non-diabetic patients treated with the TAXUS Stent from the TAXUS IV and V clinical trials. Nine-month angiographic outcomes showed equivalent in-segment late loss (0.27mm vs. 0.31mm, p=0.28) and binary restenosis (14.3% vs. 15.1%, p=0.83) in diabetics and non-diabetics, respectively.

At three years, TLR was similar for diabetic and non-diabetic patients (12.4% vs. 10.1%, p=0.25), despite significant baseline differences and increased comorbidity risk in diabetic patients. TVR was higher in diabetics (21.4% vs. 15.7%, p=0.017), due to an increase in remote TVR events (outside the stented segment), which is an indicator of the more aggressive background disease progression in diabetics. Three-year rates of stent thrombosis under Protocol definition (0.9% vs. 1.3%, p=0.63) and ARC Definite/Probable (1.6% vs. 1.9%, p=0.73) were similar, even without multivariate adjustment.

The TAXUS IV/V analysis also compared 338 diabetic patients treated with the TAXUS Stent versus 336 diabetic patients treated with bare-metal stents (BMS). Three-year rates of TVR and TLR were reduced by roughly 50 percent in diabetic patients treated with the TAXUS Stent compared to BMS, consistent with results seen in other high-risk patient groups. The TAXUS Stent showed comparable safety to BMS in diabetics, with no significant differences in death (7.3% vs. 7.1%, p=0.91), cardiac death (4.6% vs. 2.7%, p=0.23), MI (6.5% vs. 6.6%, p=0.83) or ARC Definite/Probable stent thrombosis (1.6% vs. 1.5%, p=1.00) in TAXUS and BMS, respectively.

"We are pleased to see that TLR in TAXUS patients -- an important indicator of TAXUS efficacy -- showed no significant difference between diabetic and non-diabetic patients in these studies," said Paul LaViolette, Chief Operating Officer at Boston Scientific. "This analysis is consistent with data we recently announced from our ARRIVE 1 and 2 real-world registries, showing that the TAXUS Stent effectively neutralized the impact of diabetes as a risk factor for restenosis in the patients studied."

The growing diabetic subset accounts for more than one-quarter of all coronary interventional procedures in the United States. 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.

The safety and effectiveness of the TAXUS Express Stent has not been established in patients with diabetes 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, 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 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.

(1) Rosamond W, Flegal K, Furie K, et al., "Heart disease and stroke statistics--2008 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee." Circulation. 2008;117(4):e25-146.

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