Boston Scientific

Positive Five-Year Safety Data for TAXUS® Stent Reported in Boston Scientific Trial

TAXUS IV study demonstrates long-term safety and efficacy of TAXUS drug- eluting stent compared to bare-metal stent

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(NYSE:BSX)

NATICK, Mass., and WASHINGTON, Oct. 22 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced five-year and final follow- up data from its TAXUS IV clinical trial. The benefits previously reported at years one through four -- in patients who received a TAXUS® Express™ Paclitaxel-Eluting Coronary Stent compared to patients who received a bare- metal stent (BMS) -- were maintained at five years. Stephen G. Ellis, M.D., the trial's Co-Principal Investigator and Director of the Cleveland Clinic's Sones Cardiac Catheterization Laboratories, presented the TAXUS IV five-year results at the annual Transcatheter Cardiovascular Therapeutics (TCT) symposium in Washington, D.C.

"The five-year TAXUS IV follow-up study of the TAXUS Express Stent clearly demonstrates long-term safety, with similar rates of death, myocardial infarction, and stent thrombosis across a broad cross section of patients and lesions and with no new cases of stent thrombosis between years four and five," said Gregg W. Stone, M.D., of Columbia University Medical Center and the Cardiovascular Research Foundation, New York, the Principal Investigator for the TAXUS IV clinical trial. "The TAXUS IV data combined with the TAXUS II results presented in September clearly add to the growing body of evidence reinforcing the long-term safety of TAXUS paclitaxel-eluting stents."

The results of TAXUS IV reaffirm the long-term safety of the TAXUS Stent as demonstrated by an excellent five-year safety profile. Rates of all death (10.0% vs. 11.2%, p=0.49), cardiac death (4.4% vs. 4.5%, p=0.85), and all death and Q-wave myocardial infarction (10.9% vs. 12.0%, p=0.57) were numerically lower in the TAXUS Stent group compared to the BMS group. The five-year rates of cardiac death and Q-wave myocardial infarction were identical between the TAXUS Stent and the control BMS (5.3% vs. 5.3%, p=0.96). Using the broader ARC definition of definite/probable, the TAXUS IV trial reported no cases of stent thrombosis between years four and five for the TAXUS Stent and one incidence of stent thrombosis for the BMS control group (0.0% vs. 0.2%, p=0.50), with a cumulative rate of stent thrombosis rate through five years being identical -- 2.5% for the TAXUS Stent and 2.5% for BMS (p=0.94).

"With the recent reversal of the SCAAR study, positive results from the Ontario database and excellent five-year data reported for TAXUS II and now TAXUS IV, the TAXUS Stent System has firmly established an outstanding long- term safety and efficacy record as evidenced by clinical trial data now reporting out to five years," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "Also noteworthy is that the slow-release paclitaxel-eluting TAXUS Stent continues to demonstrate its effectiveness in preventing restenosis, or additional procedures, out to five years across a wide variety of patients and lesions."

The TAXUS IV five-year results support the long-term effectiveness of the TAXUS Stent with marked target lesion revascularization (TLR) reduction across a broad cross section of patients and lesions. When compared to BMS, the TAXUS Stent reduced the five-year rates of TLR by 56% (9.1% vs. 20.5%, p<0.0001), target vessel revascularization (TVR) by 38% (16.9% vs. 27.4%, p<0.0001), and major adverse cardiac events (MACE) by 27% (24.0% vs. 32.8%, p=0.0001). The rate of patients living free of TLR events was 90.9% at five years for the TAXUS group compared to 79.5% for the BMS control group (p<0.0001). The rate of patients living free of TVR events was 83.1% at five years for the TAXUS group compared to 72.6% for the BMS control group (p<0.0001).

TAXUS IV is a randomized, double-blind pivotal trial designed to assess the safety and efficacy of a paclitaxel-eluting coronary stent system in reducing restenosis in de novo lesions 10-28 mm in length and 2.5-3.75 mm in diameter. The study, which enrolled 1,326 patients at 73 sites in the United States, had 95 percent follow-up at five years for both the paclitaxel-eluting stent and BMS populations (618 patients treated with the TAXUS Stent and 612 patients treated with BMS). The primary endpoint of the TAXUS IV clinical trial was TVR, or re-intervention, at nine months.

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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