Boston Scientific

TAXUS WOMAN Study Reports Positive Clinical Outcomes for the TAXUS® Drug-eluting Stent in Women

PRNewswire-FirstCall
NATICK, Mass. and VIENNA, Austria
(NYSE:BSX)

NATICK, Mass. and VIENNA, Austria, Sept. 5 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from the TAXUS WOMAN study, a gender specific analysis of the TAXUS II, IV, V and VI trials assessing the efficacy data of the TAXUS® paclitaxel-eluting coronary stent in women undergoing coronary revascularization. The study found paclitaxel-eluting stents to have similar clinical outcomes in women and men, despite the higher risk profile in women patients. Results of the analysis of the TAXUS WOMAN study were released at the annual European Society of Cardiology Congress in Vienna, Austria.

"This study of data from the TAXUS trials offers encouraging news for women with coronary artery disease," said Ghada Mikhail, M.D., Consultant Cardiologist, St Mary's Hospital Trust, London, UK. "Previous trials and registries have demonstrated a less favorable clinical outcome in women compared to men when undergoing coronary revascularization with bare-metal stents. That difference has been previously explained by the smaller vessels and higher risk profile seen in women. These data show, however, that the TAXUS paclitaxel-eluting coronary stent works equally well in women, maintaining its anti-restenotic efficacy advantages and positive safety profile relative to bare-metal stents."

"Heart disease is the number one cause of death among women in the United States, and more women than men die from cardiovascular disease each year," said Hank Kucheman, Senior Vice President and Group President, Interventional Cardiology. "The findings of the TAXUS WOMAN study show the clear and sustained benefit of the TAXUS Stent in women with heart disease."

The TAXUS II, IV, V and VI trials evaluated the performance of the TAXUS paclitaxel-eluting stent (PES) compared to a bare-metal stent (BMS) control in patients with coronary artery disease. The TAXUS WOMAN study analyzed pooled results of the women enrolled in these TAXUS trials and compared them with the corresponding endpoints in men.

Of the 3,445 patients enrolled in the TAXUS trials between June 2001 and March 2004, 955 (27.7%) were women. Of these women, 480 received PES and 475 received BMS. Of the 2,490 men enrolled, 1,238 received PES and 1,252 received BMS. As compared to men, women were older (mean age 65.4 +/- 10.9 years versus 61.0 +/- 10.4 years), had smaller body surface area (1.80 +/- 0.19m2 versus 2.05 +/- 0.20m2), had more diabetes (30.4% versus 21.0%), had more hypertension (78.0% versus 65.1%), had smaller vessels (pre-procedure reference vessel diameter 2.63 +/- 0.46mm versus 2.78 +/- 0.52mm), and had more history of coronary artery disease (62.2% versus 54.7%) (p for all <0.001). There were no other significant differences in baseline demographics, lesion or procedural characteristics between the PES and BMS groups in both genders.

Results show that the TAXUS Stent maintained its advantage in preventing repeat procedures compared to the bare-metal stent control, while showing no significant differences in outcomes based on gender. At one year, the unadjusted rate of target lesion revascularization (TLR) in the PES-treated group was 8.1 percent in women versus 6.7 percent in men (p=0.297), while in the BMS-treated group, the unadjusted TLR rate at one year was 17.5 percent in women versus 16.4 percent in men (p=0.613). At three years, the data showed continued low TLR rates in both women and men treated with PES (10.7% in women versus 8.8% in men, with no difference between men and women, p=0.301).

Comparable results in safety outcomes were seen for women, showing no differences in major adverse cardiac event (MACE) rates at one year. MACE rates in the PES group were 15.6 percent for women versus 13.2 percent for men (p=0.214), while MACE rate in BMS group were 24.0 percent for women versus 21.7 percent for men (p=0.332).

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, competitive offerings, procedural volume, overall market size 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 IA- 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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