Boston Scientific

Boston Scientific Announces Positive Results from its TAXUS VI Drug-Eluting Stent Trial

and Paris (May 25, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced nine-month results from its TAXUS VI clinical trial. The trial enrolled 448 patients at 44 sites in Europe, assessing the safety and efficacy of a moderate-release formulation paclitaxel-eluting stent in high-risk patients, including long lesions with overlapping stents, small vessels and diabetics. The Company made the announcement at the annual Paris Course on Revascularization, the largest interventional cardiology conference in Europe.

The randomized, double-blind trial is designed to assess a moderate-release paclitaxel-eluting coronary stent system in reducing restenosis in long de novo lesions (18 - 40 mm in length and 2.5 - 3.75 mm in diameter). The study is using Boston Scientific's TAXUS™ Express™ coronary stent system.

"These remarkable results provide strong support for the safety and efficacy of polymer-based delivery of paclitaxel in treating coronary artery disease in complex cases," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "Today's data is consistent with earlier TAXUS trials, supporting the conclusion that the moderate-release formulation is as safe and effective as the slow-release formulation. The TAXUS VI outcomes demonstrate reductions in TVR, TLR and binary restenosis similar to those trials, but in higher-risk patients. We are pleased that even in this challenging patient group, the TAXUS stent system proved particularly effective in diabetic patients. When comparing TAXUS VI to other TAXUS trials, it is important to keep in mind that TAXUS VI represents a much higher bar. For example, the average lesion length in TAXUS IV was approximately 13 mm, while in TAXUS VI it was approximately 21 mm. TAXUS VI had the longest mean lesion length and the highest-risk patient population of any drug-eluting stent trial to date, yet the results were still outstanding."

Revascularization rates

The study's primary endpoint was target vessel revascularization (symptom-driven repeat revascularization of the target vessel, or TVR). The TVR rate of 9.1 percent in the TAXUS group was significantly lower than the control group rate of 19.4 percent (P=0.0027). The study reported a target lesion revascularization (TLR) rate of 6.8 percent in the TAXUS group compared with 18.9 percent in the control group (P=0.0001). TLR - or retreatment rate - is one of the most important indicators of the performance of drug-eluting stent technology.

Safety

The results supported safety as demonstrated by low rates of Major Adverse Cardiac Events (MACE), which include death, myocardial infarction (MI; Q-wave and non-Q-wave) and TVR. The study reported a 16.4 percent MACE rate at nine months in the TAXUS group compared with 22.5 percent in the control group. This reduction was due to the lower TLR rate in the TAXUS group compared with the control group. In addition, stent thrombosis rates in the TAXUS group were low (0.5 percent or 1/219 patients) compared to the control group (1.3 percent or 3/227 patients) (p=0.62), indicating comparable safety of drug-eluting stents and bare metal stents.

Efficacy

The study reported an in-segment (stented vessel segment plus 5 mm beyond each end of the stent) binary restenosis rate of 12.4 percent in the TAXUS group compared with 35.7 percent in the control group (P=<0.0001) (binary restenosis is defined as 50 percent or greater vessel re-occlusion). The study reported an in-stent binary restenosis rate of 9.1 percent in the TAXUS group compared with 32.9 percent in the control group (P=<0.0001). In addition, the study found significant improvements in the more sensitive, quantitative angiographic measurements (in-segment, in-stent and at the edges), such as in-segment percent diameter stenosis (30.4 percent in the TAXUS group versus 45.4 percent in the control group, P=<0.0001), in-segment minimum lumen diameter (1.97 mm in the TAXUS group versus 1.51 mm in the control group; P=0.0001) and in-segment late lumen loss (0.24 mm in the TAXUS group versus 0.66 mm in the control group; P=<0.0001).

Diabetic patients

The diabetic population in the TAXUS group reported an in-segment binary restenosis rate of 10.8 percent compared with 47.6 percent in the control group (P=0.0005). Binary restenosis in the TAXUS group diabetic population was comparable to that of non-diabetic patients in the TAXUS group. Medically treated diabetic patients represent approximately 20 percent of the overall patient population in the study. The TLR rate for the medically treated diabetic sub-population of the TAXUS group was 2.6 percent compared with 22 percent in the control group (P=0.0103). Diabetic patients are more likely than non-diabetic patients to experience restenosis following angioplasty and stenting with bare metal stents, and may stand to benefit substantially from drug-eluting stent technology. In addition to the improved restenosis rates, marked improvement in late loss was also seen in the diabetic population of the TAXUS group compared to the bare metal stent control group (0.19 mm versus 0.81 mm; P= <0.0001). Diabetic patients are expected to represent approximately 40 percent of coronary interventions.

"These findings represent further evidence that the TAXUS system is effective in treating de novo coronary artery disease across a wide range of patients," said Professor Eberhard Grube, M.D., Chief of Cardiology/Angiology at the Heart Center in Siegburg, Germany, and Co-Principal Investigator of the TAXUS VI trial. "Not only did the trial meet its primary endpoint of TVR,

but the low reintervention and restenosis rates are particularly noteworthy given the average lesion length of more than 20 mm in this study."

"The low MACE, TVR and stent thrombosis rates seen in TAXUS VI demonstrate that the TAXUS stent system is safe and effective using the moderate-release formulation," said Keith Dawkins, M.D., Consultant Cardiologist, Wessex Cardiothoracic Centre Southampton University Hospital, Southampton, England, and Co-Principal Investigator of the TAXUS VI trial. "This outcome is especially significant given the higher-risk patient population studied in the trial. More importantly, it helps prove that TAXUS is safe in both slow- and moderate-release formulations."

The TAXUS technology is Boston Scientific's proprietary polymer-based, paclitaxel-eluting stent system for reducing coronary restenosis, the growth of neointimal tissue within an artery after angioplasty and stenting. Boston Scientific launched the TAXUS™ Express^2™ paclitaxel-eluting coronary stent system in Europe and other international markets in February 2003 and in the United States in March 2004. Today Boston Scientific is the global leader in the drug-eluting coronary stent market.

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.

This press release contains forward-looking statements. The Company wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with clinical trials, the regulatory approval process, commercialization of new technologies, intellectual property, and other factors described in the Company's filings with the Securities and Exchange Commission.
