Boston Scientific

Boston Scientific Announces Sub-Population Data from its TAXUS VI Drug-Eluting Stent Trial

and Paris (May 26, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced nine-month sub-population data 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. Analysis of the sub-population data was presented by TAXUS VI Co-Principal Investigators Professor Eberhard Grube, M.D. and Keith Dawkins, M.D., as well as Investigator Jeffrey Popma, M.D. and Mary Russell, M.D., Boston Scientific Senior Vice President and Chief Medical Officer for Cardiovascular Clinical Sciences. 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.

Patients with long lesions and overlapping stents

The TAXUS VI results support the safety and efficacy of the TAXUS system in patients with long lesions requiring the use of overlapping stents. Twenty-eight percent (124 of 448) of the patients had long lesions with overlapping stents. The study's patient population had an average lesion length of approximately 21 mm. The target lesion revascularization (TLR) rate for the TAXUS group was 1.6 percent compared with 23.0 percent in the control group (P=<0.0001). The target vessel revascularization (TVR) rate of 1.6 percent in the TAXUS group was significantly lower than the control group rate of 24.6 percent (P=<0.0001). The study reported an in-segment binary restenosis rate of 8.1 percent in the TAXUS group compared with 50.9 percent in the control group (P=<0.0001). The study reported an in-stent binary restenosis rate of 4.8 percent in the TAXUS group compared with 45.5 percent in the control group (P=<0.0001). Late loss improvement was also seen in the TAXUS group compared to the control group (.24 mm versus .86 mm; P=<0.0001).

Patients with small vessels

The small vessel sub-population consisted of 124 patients (28 percent) whose average reference vessel diameter was less than 2.5 mm. This sub-population reported a TLR rate of 5.0 percent in the TAXUS group compared with 29.7 percent in the control group (P=0.0003). The TVR rate of 8.3 percent in the sub-population's TAXUS group was lower than the control group rate of 31.3 percent (P=0.0016).

The small vessel sub-population also reported an in-segment (stented vessel segment plus 5 mm beyond each end of the stent) binary restenosis rate of 10.9 percent in the TAXUS group compared with 45.6 percent in the control group (P=<0.0001) (binary restenosis is defined as 50 percent or greater vessel re-occlusion). The subset reported an in-stent binary restenosis rate of 7.3 percent in the TAXUS group compared with 40.4 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) of the small vessel sub-population, such as in-segment late lumen loss (0.03 mm in the TAXUS group versus 0.53 mm in the control group; P=<0.0001).

Diabetic patients

The diabetic sub-population analysis demonstrated significant improvements among diabetic patients receiving the TAXUS system versus those in the control group. Diabetic patients represent approximately 20 percent (89 of 448) of the overall patient population in the study. 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.

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). The TVR rate of 7.7 percent in the subset

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