

## **TAXUS V Demonstrates Excellent Safety and Efficacy Results in Most Challenging Lesions and High-Risk Patients**

and Orlando, FL (March 6, 2005) -- Boston Scientific Corporation (NYSE: BSX) today announced nine-month results from its TAXUS V clinical trial, confirming the safety and efficacy of the TAXUS® Express<sup>2</sup>™ paclitaxel-eluting coronary stent system for the treatment of coronary artery disease. The Company said that the overall TAXUS V study met its primary endpoint as well as all secondary endpoints. TAXUS V expands on the TAXUS IV pivotal trial by studying a higher-risk patient population, including patients with small vessels, large vessels and long lesions requiring multiple overlapping stents -- the most challenging lesions and highest-risk patients ever studied in a randomized, controlled drug-eluting stent trial in the United States. The Company made the announcement at the annual American College of Cardiology scientific session in Orlando.

The randomized, double-blind trial enrolled 1,172 patients at 66 sites in the United States, assessing the safety and efficacy of a slow-release formulation paclitaxel-eluting coronary stent system in reducing restenosis in de novo lesions 10 - 46 mm in length and 2.25 - 4.0 mm in diameter.

### **Comparable safety data**

The results supported safety as demonstrated by low overall rates of Major Adverse Cardiac Events (MACE) and stent thrombosis. MACE includes death, myocardial infarction (MI; Q-wave and non-Q-wave) and target vessel revascularization (TVR). The study reported a 15.0 percent overall MACE rate at nine months in the TAXUS group compared with 21.2 percent in the control bare-metal stent group ( $p=0.0084$ ), with all other factors, including cardiac death and MI, comparable to control (cardiac death was 0.5 percent in the TAXUS group versus 0.9 percent in the control group ( $p=0.7256$ ), MI was 5.4 percent in the TAXUS group versus 4.6 percent in the control group ( $p=0.5853$ )). The MACE reduction was due to the lower target lesion revascularization (TLR) rate in the TAXUS group compared with the control group. In addition, stent thrombosis rates were identical between TAXUS and control stents (0.7 percent or 4/557 patients in the TAXUS group versus 0.7 percent or 4/562 patients in the control group), indicating comparable safety of drug-eluting stents and bare-metal stents.

### **Excellent revascularization rates**

The study reported a TLR rate of 8.6 percent in the TAXUS group compared with 15.7 percent in the control group ( $P=0.0003$ ). TLR - or retreatment rate - is one of the most accurate indicators of the performance of drug-eluting stent technology. The study met its primary endpoint, nine-month TVR (symptom-driven repeat revascularization of the target vessel), which was significantly lower in the TAXUS group (12.1 percent) than in the control group (17.3 percent) ( $p=0.0184$ ).

### **Reduced restenosis rates**

The study reported an in-segment (stented vessel segment plus 5 mm beyond each end of the stent) binary restenosis rate of 18.9 percent in the TAXUS group compared with 33.9 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 13.7 percent in the TAXUS group compared with 31.9 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 (33.63 percent in the TAXUS group versus 42.34 percent in the control group;  $P<0.0001$ ), in-segment minimum lumen diameter (1.81 mm in the TAXUS group versus 1.57 mm in the control group;  $P<0.0001$ ) and in-segment late lumen loss (0.33 mm in the TAXUS group versus 0.60 mm in the control group;  $P<0.0001$ ).

"These are extraordinary results, especially given the challenging lesions and high-risk patients," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "TAXUS V has raised the bar on randomized, controlled drug-eluting stent clinical trials. It is the latest example of the unsurpassed rigor, depth and breadth of the TAXUS program, and it is a breed apart from other trials. We are pleased the TAXUS V data is consistent with data from other TAXUS trials, and proud that it will help advance knowledge about the applications of drug-eluting stent technology."

"TAXUS V studies a challenging patient population with multiple, concurrent risk factors including small vessels and long lesions requiring multiple stents, which has never before been studied with drug-eluting stents," said Gregg W. Stone, M.D., the study's Principal Investigator and Professor of Medicine, Columbia University Medical Center in New York. "The overall study shows TAXUS stents are safe, with comparable rates of death, MI and stent thrombosis between TAXUS and bare-metal stents. The study further shows the product is highly effective, with marked reductions in clinical and angiographic parameters. While there was a small but elevated rate of non-Q-wave MI in TAXUS patients receiving multiple overlapping stents compared to control, this was most likely related to reductions in side branch blood flow and balanced by the reduction in reintervention of more

than 50 percent in the TAXUS group."

"These are compelling findings that further confirm the safety outcomes of paclitaxel-eluting stent technology compared to bare-metal stents," said Stephen G. Ellis, M.D., the trial's Co-Principal Investigator and Director of the Sones Cardiac Catheterization Laboratories at the Cleveland Clinic. "The overall MACE rates are particularly low for such a complex set of patients. TAXUS V breaks new ground in examining this high-risk patient population."

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](http://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.

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