Boston Scientific

TAXUS VI Clinical Trial Demonstrates Positive Long-Term Outcomes for Moderate-Release Paclitaxel-Eluting Stent at Four Years

Trial results report no new stent thrombosis after two years in high-risk patient population

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NATICK, Mass., and BARCELONA, Spain, May 22 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced four-year follow-up data from its TAXUS VI clinical trial. The data demonstrated that the safety and efficacy benefits associated with a moderate-release formulation of the TAXUS® Express™ paclitaxel-eluting stent system -- which is not approved for commercial distribution -- were maintained at four years with no new stent thrombosis reported after two years. Analysis of the data was presented by Professor Eberhard Grube, M.D., Heart Center Siegburg, Germany, the Co- Principal Investigator of the trial. The Company made the announcement at the annual Paris Course on Revascularization (EuroPCR) in Barcelona.

"Even though the moderate-release TAXUS formulation, with an 8-10 fold higher in vitro dose, was never commercialized, the excellent ongoing results in TAXUS VI further demonstrate the margin of safety of the commercial slow- release TAXUS stent now implanted in more than four million patients worldwide," said Paul LaViolette, Boston Scientific Chief Operating Officer. "With no stent thrombosis after two years, a low cardiac death rate, and a low TLR rate, we continue to be impressed with how paclitaxel performs in this high-risk patient population."

"The four-year results from TAXUS VI demonstrate that the safety and efficacy benefits associated with the moderate-release TAXUS paclitaxel- eluting stent system were maintained in patients with complex coronary artery disease at four years," said Professor Grube. "The performance of the TAXUS stent in these patients was extremely impressive when considering the complexity of their disease, including patients with long lesions, small vessels, and those requiring multiple, overlapping stents."

The randomized, double-blind, controlled study of 446 patients at 44 international sites is designed to assess the TAXUS moderate-release paclitaxel-eluting coronary stent system in reducing restenosis in high-risk patients, including de novo lesions with overlapping stents, lesions 26 mm or greater in length and small vessels. Lesion size ranged from 18 - 40 mm in length and 2.5 - 3.75 mm in diameter. TAXUS VI is the first randomized, controlled clinical trial to demonstrate durability of drug-eluting stents in complex lesions at four years. Follow-up included 98 percent of the patients enrolled at four years.

The study's results demonstrate a continued significant reduction in target lesion revascularization (TLR, or retreatment rate) as compared to the bare-metal stent control group at four years. The four-year TLR rate was 12.9 percent for the TAXUS Stent group, as compared with 21.4 percent for the control group (P=0.0082 (only two TLR events were reported between three and four years for the TAXUS Stent group)). The rate of patients living free of TLR events was 87.1 percent at four years for the TAXUS Stent group, as compared to 78.6 percent for the bare-metal stent control group.

The four-year results for TAXUS VI support long-term safety with the increased levels of paclitaxel in the moderate-release formulation used in the study. Even with an in vitro dosing rate 8-10 times greater than the commercialized slow-release formulation, no compromise in safety was observed. The TAXUS Stent group continues to report no new stent thrombosis after two years with a low 2.4 percent cardiac death rate.

Boston Scientific launched the slow-release formulation TAXUS Express2 paclitaxel-eluting coronary stent system in Europe and other international markets in 2003 and in the United States in 2004. The Company launched the slow-release formulation TAXUS® Liberte™ paclitaxel-eluting coronary stent system in Europe and other international markets in 2005. The TAXUS Express moderate-release paclitaxel-eluting stent is not approved for commercial distribution.

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/ .

This press release contains forward-looking statements. Boston Scientific 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 new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Dan Brennan
508-650-8538 (office)
617-459-2703 (mobile)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Media Relations, Paul Donovan, +1-508-650-8541, mobile,
+1-508-667-5165, Investor Relations, Dan Brennan, +1-508-650-8538, mobile,
+1-617-459-2703, both of Boston Scientific Corporation

Web site: http://www.bostonscientific.com/
