Boston Scientific

Moderate-Release TAXUS® Express™ Coronary Stent System Demonstrates Sustained Long-Term Outcomes in High-Risk Patients

NATICK, Mass. and PARIS, May 16 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced three-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 were maintained at three years. Analysis of the data was presented by Keith D. Dawkins, M.D., Co-Principal Investigator of the trial. The Company made the announcement at the annual Paris Course on Revascularization (EuroPCR).

The randomized, double-blind, controlled study of 448 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 long de novo lesions with overlapping stents, small vessels and diabetics. 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 three years. Follow-up included 98.2 percent of the patients enrolled at three years (432 out of 440).

"The three-year data from TAXUS VI demonstrates sustained safety and efficacy of the moderate-release TAXUS paclitaxel-eluting stent system in patients with long lesions treated with multiple, overlapping stents," said Dr. Dawkins. "It's reassuring to see that even in the most complex lesions ever studied in a drug-eluting stent trial, moderate-release TAXUS stents offer sustained target lesion revascularization benefits over time with no compromise to safety."

"The TAXUS VI results show continuing patient benefits in the longest lesions ever studied in a randomized clinical trial," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "This data is consistent with the strong, long-term safety and efficacy results seen with the slow-release TAXUS formulation and attests to the durability of the moderate-release technology even among this high-risk patient population."

Continued efficacy

The study's results indicate a continued significant reduction in target lesion revascularization (TLR, or retreatment rate) as compared to the bare-metal stent control group at three years. The study reported a three-year TLR rate of 11.7 percent (25/213) for the TAXUS group, as compared with 21.2 percent (46/217) for the control group (P=0.0082) (only four TLR events were reported between two and three years for the TAXUS group). The rate of patients living free of TLR events was 88.4 percent at three years for the TAXUS group, as compared to 79.1 percent for the bare-metal stent control group.

Long-term safety

The three-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. Stent thromboses remained unchanged between two and three years at a low 0.9 percent for both the TAXUS group and the control group.

Boston Scientific launched the slow-release formulation TAXUS Express2 paclitaxel-eluting coronary stent system in Europe and other international markets in February 2003 and in the United States in March 2004. 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: Milan Kofol
508-650-8569 (Office)
Investor Relations
Boston Scientific Corporation

Charles Rudnick
508-650-8660 (Office)
617-935-1789 (Mobile)
Media Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Milan Kofol, Investor Relations, +1-508-650-8569, or Charles Rudnick, Media Relations, +1-508-650-8660, cell: +1-617-935-1789, both of Boston Scientific Corporation

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

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