Boston Scientific

Safety and Efficacy Benefits of Next-Generation TAXUS® Liberte™ Stent Sustained at Twelve Months

PRNewswire-FirstCall
NATICK, Mass., and WASHINGTON
(NYSE:BSX)

NATICK, Mass., and WASHINGTON, Oct. 25 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced 12-month follow-up data from TAXUS ATLAS, the pivotal clinical trial evaluating the TAXUS® Liberte™ paclitaxel-eluting stent system. The data demonstrated that the safety and efficacy benefits associated with the TAXUS Liberte Stent System at nine months were maintained at 12 months in workhorse lesions. The results were presented by Mark Turco, M.D., Director of the Center for Cardiac and Vascular Research, Washington Adventist Hospital, and co-principal investigator of the trial, at the Cardiovascular Research Foundation's (CRF) eighteenth annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

"The TAXUS ATLAS Workhorse trial results are extremely compelling and the data from the TAXUS Liberte stent in this study suggest safety and efficacy comparable to the TAXUS® Express™ stent in the treatment of coronary artery disease," said Dr. Turco. "We are also seeing significant advantages in the deliverability and conformability of the more flexible TAXUS Liberte stent as compared to the TAXUS Express stent."

"We are extremely pleased with positive safety and efficacy results of the TAXUS ATLAS trial, which reinforce the overall benefit provided by drug-eluting stents in the treatment of coronary artery disease," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "These favorable outcomes for our next-generation Liberte stent -- currently the market-leader in Europe -- together with the recent CE Mark approval of our everolimus-eluting PROMUS™ stent system, illustrate our unparalleled pipeline of DES technologies."

While identical inclusion and exclusion criteria were used for both the TAXUS Liberte stent and the TAXUS Express stent historical control group, more complex lesions were treated with the TAXUS Liberte stent than with the TAXUS Express stent. Despite this difference, the study reported comparable results in clinical outcomes between both groups. The study reported a low 12-month overall cardiac death rate of 0.8 percent for the TAXUS Liberte stent, as compared to 1.0 percent for the control group (P=0.62). The study also reported an overall myocardial infarction (MI) rate of 4.0 percent for the TAXUS Liberte stent group, as compared to 3.9 percent for the control group (P=0.89). The overall rate of stent thrombosis at 12 months for the TAXUS Liberte stent group was 0.9 percent, as compared to 0.7 percent for the control group (P=0.63). The TAXUS ATLAS trial reported an overall target vessel revascularization (TVR) rate of 9.2 percent for the TAXUS Liberte stent group, as compared to 8.9 percent for the control group (P=0.83) at 12 months. TAXUS ATLAS, a global, multi-center, single-arm study enrolling 871 patients at 61 sites, was designed to demonstrate that the TAXUS Liberte stent is non-inferior in safety and efficacy to the TAXUS Express stent.

This trial compares patients with de novo coronary lesions treated with the TAXUS Liberte stent to a historical case-matched TAXUS Express stent control group derived from TAXUS IV and TAXUS V de novo. The TAXUS ATLAS trial met its primary endpoint of nine-month TVR non-inferiority, in spite of more complex patients treated with the TAXUS Liberte stent. Similar rates of TVR were maintained at 12 months.

Clinical follow-up at 12 months in the TAXUS Liberte stent arm of the TAXUS ATLAS trial included 98.7 percent of patients receiving the study stent (856/867).

Positive results also reported for TAXUS ATLAS DIRECT STENT

Boston Scientific also announced nine-month data from its TAXUS ATLAS DIRECT STENT clinical trial. The TAXUS ATLAS DIRECT STENT trial is a 247-patient, global, multi-center, single-arm study of the TAXUS Liberte paclitaxel-eluting coronary stent system for the treatment of patients with de novo coronary artery lesions using the direct stenting (no balloon pre-dilatation of the vessel prior to stenting) deployment technique. The study assessed the safety of direct stenting compared to placement of a stent using balloon pre-dilatation. The control arm for the trial is the angiographic cohort of the TAXUS ATLAS WORKHORSE clinical trial, which mandated pre-dilatation. Although the TAXUS ATLAS and TAXUS ATLAS DIRECT trial had the same inclusion and exclusion criteria, simpler lesions were selected for the direct stent group.

"We saw significantly less target lesion revascularization (TLR), target vessel revascularization (TVR) and major adverse cardiac events (MACE) rates for the direct stent group as compared to the pre-dilatation control group," said John Ormiston, M.D., co-principal investigator of both the TAXUS ATLAS DIRECT STENT trial and the TAXUS ATLAS WORKHORSE study, and Interventional Cardiologist, Mercy Hospital and Green Lane Cardiovascular Unit, Auckland, New Zealand. "Overall, the trial suggests that the direct stenting method using the TAXUS Liberte stent is as safe and effective as stenting with pre-dilatation."

The study reported a success rate of 97.6 percent for delivery of the TAXUS Liberte stent by direct stenting, and a shorter

procedure time for patients assigned to receive intravascular ultrasound during the index procedure. The study reported a low nine-month overall cardiac death rate of 0.8 percent for the direct stent group, as compared to 1.3 percent for the control group (P=0.73). The study also reported an overall myocardial infarction (MI) rate of 4.5 percent for the direct stent group, as compared to 4.3 percent for the control group (P=0.87). The rate of stent thrombosis for the direct stent group was 0 percent, as compared to 0.9 percent for the control group (P=0.33). The rate of target vessel revascularization was 5.0 percent for the direct stent group, as compared to 11.2 percent for the control group (P=0.0056). The rate of MACE was 9.1 for the direct stent group, as compared to 14.7 for the control group (P=0.0307). The rate of target lesion revascularization was 2.9 percent for the direct stent group, as compared to 7.8 percent for the control (P=0.0087).

The study met its primary endpoint of non-inferiority of in-segment percent diameter stenosis (by QCA) at nine months.

The Company received the CE Mark for the TAXUS Liberte stent in Europe and other international markets in September 2005, and it is currently the market-leading drug-eluting stent outside the United States (the TAXUS Liberte stent is not available for sale in Japan). The TAXUS Liberte stent is not indicated for direct stenting in the European Union. The TAXUS Liberte stent is currently pending approval by the U.S. Food and Drug Administration and is not available for sale in the United States. The Company plans to launch the TAXUS Liberte stent in the United States in 2007. The Company received the CE Mark for its everolimus-eluting PROMUS stent in October 2006 and plans to launch the PROMUS stent in Europe in early 2007, making Boston Scientific the only company to offer two distinct drug-eluting stent platforms. The PROMUS stent, a private-label XIENCE™ V Everolimus Eluting Coronary Stent System, is manufactured by Abbott and distributed by Boston Scientific. The PROMUS stent is not available for sale in the United States.

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. 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, reimbursement policies, commercialization of new technologies, litigation, the Company's overall business strategy and other factors described in the Company's filings with the Securities and Exchange Commission.

CONTACT:
Milan Kofol
508-650-8569 (Office)
617-834-8595 (Mobile)
Investor Relations
Boston Scientific Corporation

Paul Donovan
508-650-8541 (Office)
508-667-5165 (Mobile)
Media Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Milan Kofol, +1-508-650-8569 (Office) or 617-834-8595 (Mobile), Investor Relations, or Paul Donovan, +1-508-650-8541 (Office), or +1-508-667-5165 (Mobile), Media Relations, both of Boston Scientific Corporation

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

---

https://news.bostonscientific.com/safety-efficacy-nextgen-taxus-twelve-months