Boston Scientific

Boston Scientific Announces Two-Year Follow-Up Data from TAXUS II Clinical Trial

and Washington, D.C. (September 29, 2004) -- Boston Scientific Corporation (NYSE: BSX) today announced two-year follow-up data from its TAXUS II paclitaxel-eluting stent system clinical trial. The results provided two-year clinical outcomes, as well as the largest, long-term prospective quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS) follow-up data of any drug-eluting stent trial to date. The data demonstrated that the safety and efficacy benefits associated with the TAXUS stent system were maintained at two years. The Company made the announcement at the annual Transcatheter Cardiovascular Therapeutics symposium in Washington, D.C.

"The two-year data from TAXUS II clearly demonstrate the sustained safety and effectiveness of the TAXUS paclitaxel-eluting stent system in the treatment of de novo coronary artery disease," said Professor Antonio Colombo, M.D., Columbus Hospital and San Rafaelle Hospital in Milan, the trial's Principal Investigator. "This data indicates that TAXUS stents may prevent - rather than merely delay - in-stent restenosis. The large patient cohorts and long-term angiographic and IVUS data provide an especially rich source of information on the excellent performance of the TAXUS system."

"These results extend out to two years the earlier conclusions of improved clinical outcomes for the TAXUS system," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "I am especially pleased that the benefits associated with TAXUS - reduced restenosis rates and continued safety - were shown to be maintained by the longest-term angiographic data yet released on drug-eluting stent technology."

Efficacy
The study's results indicate a continued significant difference for both the slow- and moderate-release formulation cohorts in target lesion revascularization (retreatment rate, or TLR) as compared to the combined control group. The study reported a TLR rate of 5.5 percent (7/127) for the slow-release formulation cohort and 3.9 percent (5/127) for the moderate-release formulation cohort, as compared with 15.5 percent (41/264) for the combined control group. This included eight new TLR events (percutaneous coronary intervention, or PCI) between one and two years in the combined control group compared to one new event in the slow-release formulation group and no new events in the moderate-release fomulation group.

The TAXUS II two-year follow-up included the largest prospective angiographic and IVUS two-year sub-study population (210 patients) in interventional cardiology. Angiographic data demonstrated stable late loss out to two years with sustained statistical benefit over the control group. The benefit in percent net volume obstruction as the primary endpoint at six months was also maintained out to two years, as demonstrated by the IVUS sub-study data.

Safety
The two-year results for TAXUS II support long-term safety, as incidences of aneurysms, incomplete apposition (separation of the stent from the vessel wall) and stent thromboses were all low and comparable to control rates. No new aneurysms were seen at two years. Incidence of incomplete apposition was 8.7 percent for the slow-release formulation cohort and 6.5 percent for the moderate-release formulation cohort, versus 9.0 percent for the combined control group.

TAXUS II is a 536-patient, 15-country, randomized, double-blind, controlled study of the safety and efficacy of a TAXUS paclitaxel-eluting coronary stent, in which two sequential cohorts of patients with standard risk, de novo coronary artery lesions were treated with two different dose formulations: slow-release (SR) and moderate-release (MR). The study met its primary endpoint - six-month, percent in-stent volume obstruction as assessed by IVUS - in results announced in September 2002. In March 2003, Boston Scientific announced one-year follow-up data from TAXUS II, which supported safety and efficacy. In May 2003, the Company announced additional results related to higher-risk patient subgroups, including diabetics and patients with longer lesions and smaller vessels, demonstrating that the reduction in target lesion revascularization (TLR) events for the TAXUS II subgroups at one year was equal to or better than that of the general study population. It also announced data in May 2003 demonstrating excellent performance by the TAXUS stent at six months with respect to vascular healing, incomplete apposition and edge effect following detailed IVUS analysis. The Company has commercialized the slow-release formulation; the moderate-release formulation is not available for commercial distribution. At two years, patients returned for clinical follow-up and approximately 50 percent of patients were enrolled in a special angiographic and IVUS sub-study to better ascertain the longevity of the safety and efficacy outcomes seen at six months. Clinical follow-up in TAXUS II included 96 percent of the patients enrolled at two years (512/536). The follow-up rate for angiographic IVUS examinations was 231/536, resulting in different "denominators" for the follow-up subgroups.

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.

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 the commercialization of new technologies, competitive offerings, intellectual property and other factors described in the Company's filings with the Securities and Exchange Commission.

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