Boston Scientific Welcomes New England Journal of Medicine Articles on Drug-Eluting Stents

NATICK, Mass., Feb. 12 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed the online release of several important articles scheduled for publication in the March 8th edition of the New England Journal of Medicine (NEJM). These articles confirm the safety and efficacy of the Company's TAXUS® Express2™ paclitaxel-eluting coronary stent system (TAXUS Stent) when used for the indications included in its approved labeling. The TAXUS Stent was approved by the U.S. Food and Drug Administration (FDA) in March 2004 for use in first-time lesions up to 28 mm in length in coronary vessels between 2.5 and 3.5 mm in diameter.

In total, the findings support Boston Scientific's own internal analyses, publications, physician communications and public presentations of the TAXUS trial data, showing that patients who received the TAXUS Stent for on-label indications had nearly a 50 percent reduction in the need for repeat procedures to treat vessel renarrowing, with no increase (in-fact a slight numerical decrease) in the risk of all-cause death or large heart attack, compared to the patients who had received the "control" bare-metal stent (BMS). These findings had previously been verified by independent examination of the data, and are now further confirmed by the additional independent analyses reported by Drs. Mauri et al, and Dr. Stone et al in the NEJM.

"This collection of information extends and solidifies our understanding of the role of drug-eluting stents by reaffirming the small magnitude of any increase in stent thrombosis, confirming the absence of an associated significant risk of death or heart attack for on-label indications, and calling for individualized physician decisions regarding the use of drug- eluting stents versus alternative revascularization approaches in currently off-label or extended use, until definitive trials for those uses are completed," said Donald S. Baim, M.D., Chief Medical and Scientific Officer for Boston Scientific.

Dr. Gregg Stone from Columbia University and the Cardiovascular Research Center and his co-authors examined patient level data on 3,513 patients from five clinical trials that randomly assigned them to receive either the TAXUS Stent (1,755 patients, including a small number who received a purely investigational higher dose - or moderate-release (MR) - formulation) or a similar bare-metal control stent (1,758 patients). These patients were then followed for up to four years, at which time the TAXUS Stent patients had a nearly 50 percent reduction (from 20.0%, to 10.1%) in the need for a repeat procedure to treat a renarrowing, and a trend toward lower rates of death (6.1% v. 6.6%) (p=0.68) and death or large (Q-wave) heart attack (7.3% vs. 7.5%) (p=0.93), compared to the patients who received the bare-metal control stent. Using the original protocol definition, there was a slight numerical excess of stent clotting (1.3% in the TAXUS Stent arm, versus 0.9% in the bare-metal arm), which failed to reach statistical significance (p=0.30). Looking only at thrombosis events occurring beyond the first year, and including both moderate- and slow-release versions of the TAXUS stent, the study confirmed the previously reported small (0.4%, or about one event per 500 patient years) but statistically significant (p=0.028) increase for the TAXUS Stent compared to the bare-metal control stent, which Boston Scientific's investigators have reported since March 2005. Similar examination comparing 878 patients who received Cordis' Cypher® sirolimus- eluting coronary stent (Cypher Stent) to 870 patients who received a bare- metal control stent also showed a significant reduction in repeat procedures, but showed a trend toward higher rates of death (6.7% vs. 5.3%) (p=0.23) and death or large (Q-wave) MI (8.2% vs. 6.4%) (p=0.14), and a similar and equally statistically significant (0.6%, p=0.025) increase in stent thrombosis after one year for the Cypher Stent compared to the bare-metal control stent.

Dr. Christian Spaulding and co-authors from the Thoraxcenter in Rotterdam also examined the same patient level data on 878 patients who received the Cypher Stent and 870 patients who received a bare-metal control stent. Their findings were similar to those of Stone et al regarding the slight but not statistically significant increased incidence of death (6.7% vs. 5.4%) (p=0.28) and death or Q-wave heart attack (8.2% vs. 6.5%) (p=0.17) in the Cypher Stent compared to the bare-metal group. In the subgroup of 428 patients with diabetes, however, there was a highly significant increase in death for patients treated with the Cypher Stent versus the bare-metal control stent (12.2% versus 4.4%) (p=0.008). At the December 7-8 FDA advisory panel meeting on drug-eluting stents (DES), Boston Scientific had presented data that the 715 patients with diabetes in its TAXUS Stent trials had similar or lower rates of death (9.2% DES vs. 10.7% BMS) (p=0.78), with a significant reduction in repeat procedures (13.4% vs. 24.9%) (p<0.0001), for the TAXUS Stent versus the bare-metal control stents, up to four years of follow up.(1)

Dr. Adnan Kastrati and co-authors reported a separate meta-analysis of clinical trials assessing the relative safety of the Cypher Stent versus bare- metal stents (some with follow up as short as 12 months), and confirmed the trend toward excess mortality for the Cypher Stent versus BMS in diabetics, which did not show statistical significance as seen in the Dr. Patrick Serruys analysis of four Cordis pivotal trials at four-year follow up.

Dr. Laura Mauri and co-authors from the Harvard Clinical Research Center examined patient-level data from a sub-set of 2,797 patients who were randomly assigned to receive either the commercialized (slow-release, or SR) formulation of the TAXUS Stent or a similar BMS, and then followed for up to four years. Instead of the original (protocol) definition of stent thrombosis, they used the Academic Research Consortium (ARC) definitions of definite or probable stent thrombosis, and found no statistically significant differences in stent clotting overall for either the TAXUS Stent or the Cypher Stent compared to their respective bare-metal controls. Cumulatively in years one through four, the rates of stent thrombosis were 0.9% for the TAXUS

Stent vs. 0.6% for BMS, and 0.9% for Cypher vs. 0.4% for BMS.

These observations were echoed in a Perspective piece in the March 8th edition of the NEJM by Dr. Andrew Farb and Ashley Boam (both of the FDA), who also summarized the findings of the FDA advisory panel, writing: "when drug- eluting stents are used for their approved indications, the risk of thrombosis does not outweigh their advantages over bare-metal stents in reducing the rate of repeated revascularization." In addition, the authors emphasized that further " ... randomized controlled trials ... are needed to determine the best treatment strategies for lesions in patients with common, complex conditions" in which drug-eluting stents are now used beyond the current label indications. As examples, they cited three such trials that are already ongoing with Boston Scientific support, comparing drug-eluting stents to therapeutic alternatives in patient groups that lie outside current label indications.

Dr. Bo Lagerqvist, et al authored an article in the same edition of the NEJM describing results from the Swedish Coronary Angiography and Angioplasty Registry, which is the subject of a separate Boston Scientific press release today.

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 product development and commercialization, clinical trials, regulatory approvals, competitive offerings, intellectual property, the company's overall business strategy and other factors described in the Company's filings with the Securities and Exchange Commission.

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(1) The Company is currently sponsoring the collection of clinical data to support an application to the U.S. Food and Drug Administration to expand the TAXUS Stent's labeled indications for use in the United States to include diabetic patients. The safety and effectiveness of the TAXUS Express™ Stent have not been established in patients with diabetes.

SOURCE: Boston Scientific Corporation

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