Boston Scientific

Boston Scientific Comments on Swedish Registry Results

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NATICK, Mass., Feb. 12 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today commented on results from a Swedish registry assessing the long-term outcomes of drug-eluting stents (DES) versus bare- metal stents (BMS) that were released online today and are scheduled for publication in the March 8th edition of the New England Journal of Medicine.

"The Swedish registry data are provocative, but far from definitive," said Donald S. Baim, M.D., Chief Medical and Scientific Officer for Boston Scientific. "The raw data showed no increase in death or heart attack for drug-eluting stents, and a small increase was suggested only after statistical adjustment was performed in an effort to correct for the significantly greater number of high-risk patients in the drug-eluting stent group. In addition, the counting of adverse events was restarted beyond the first six months, after drug-eluting stents have already provided their greatest benefit."

Writing in an accompanying Perspective piece in the March 8th edition, Dr. William H. Maisel, M.D., M.P.H, and the chairman of the December 7-8 U.S. Food and Drug Administration (FDA) advisory panel meeting on DES, made the following comment about the Swedish registry: "Stent selection, however, was not randomized among registry patients, so the observed differences may be due to confounding factors such as physician bias in stent preference. Thus, current data are inadequate for assessment of the relative benefit of off- label use of drug-eluting stents as compared with either bare-metal stents or coronary-artery bypass surgery."

The registry was designed as a non-randomized, observational assessment combining the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) with other national health outcome databases, to track the outcomes of nearly 20,000 patients receiving DES or BMS in 2003 and 2004. The authors report similar rates for the composite primary endpoint of death and myocardial infarction (MI, or heart attack) in DES and BMS patients over a median follow- up of 1.5 years and a maximum follow-up of three years after stent implantation.

The Swedish registry findings are consistent with results from numerous recently published studies in Europe and the U.S. that show superior efficacy (a reduced need for revascularization) and comparable safety (no net increase in death or myocardial infarction) for DES relative to BMS. Those studies include the Dutch TSEARCH/RESEARCH registry with more than 2,500 patients(1), the Swiss BASKET study(2) with more than 800 patients, the Italian REAL registry with more than 1,600 patients(3), the U.S. DEScover registry with nearly 7,000 patients(4), and the recently published randomized clinical trial meta-analysis by a study group at the Basel Institute for Clinical Epidemiology(5) in Switzerland, with more than 8,000 patients. The U.S. Wake Forest registry with nearly 2,500 patients(6) actually reported a statistically significant lower death and myocardial infarction rate for DES when compared to BMS.

Additional analyses by the Swedish registry group of individual secondary endpoints at select time intervals underscore the scientific limitations of using retrospective, non-randomized, observational assessments to generate data for prospective risk assessment. More specifically, only when statistical adjustments were performed to correct significant baseline imbalances in the DES and BMS groups, and analysis was confined to a time window from six months to three years, did the Swedish study group identify a slightly higher risk ratio for death in the DES group. These results stand in sharp contrast to several previously described registries finding no difference in death or myocardial infarction rates with DES when compared to BMS, and the finding of slightly (but not statistically significantly) lower death and large (Q-wave) heart attack rates in the DES compared to the BMS arm of the randomized TAXUS clinical trials in nearly 3,500 patients.

In part, the conflicting findings of the Swedish study might be explained by substantial differences in patient, lesion and procedural characteristics known to be predictive of higher adverse outcomes between those patients treated with DES and those treated with BMS. For example, the DES cohort had a 1.5 times higher (nearly 10% higher absolute) incidence of diabetic patients than the BMS cohort. Lesion coverage required multiple stents in 1.6 times more patients in the DES group, and the use of long stents or small diameter stents were 2.8 times higher in the DES group. The rate of left main lesions was 2.3 times higher. Past studies have established each of these parameters as independent predictors of higher incidences for death or myocardial infarction. On the other hand, more patients in the BMS arm underwent stent placement for heart attack treatment. A similar pattern has been observed consistently in other sequential (non-randomized) registries performed since the introduction of DES, since DES are routinely used to treat more complex patients than are treated with BMS. While using statistical adjustment methods to take into account some of these differences, the authors acknowledge the potential of additional confounding effects by characteristics that were not captured in the underlying database.

Overall, the Swedish registry further illustrates the strengths and weaknesses of so-called "real-world" registries when compared to prospective, randomized and actively controlled trials. The recommendations of the FDA advisory panel underline the need for blinded, randomized, actively controlled, prospective multi-center trials to further characterize long-term outcomes for current DES, especially in the complex groups of patients being treated beyond the current on-label indications. As

described in a Perspective piece by two FDA officials in the same edition of the New England Journal of Medicine, a number of large prospective trials studying DES in patients with acute myocardical infarction, multi-vessel disease (with and without diabetes mellitus) and in patients with disease of the left main coronary artery, are under way trying to answer these questions. Boston Scientific is a sponsor or major financial supporter of these trials, and is actively working on developing a sufficient evidence base to demonstrate the safety and efficacy of its TAXUS stent system in these clinical conditions to allow expansion of the current indications for DES.

The TAXUS Express2™ paclitaxel-eluting coronary stent system has not been proved safe and effective for use outside its FDA-approved indications.

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.

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

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

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