Boston Scientific

Safety and Efficacy of Drug-Eluting Stents Reaffirmed in New England Journal of Medicine Articles and Editorial

NATICK, Mass., Sept. 13 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed the results of two studies and an editorial published in today's edition of The New England Journal of Medicine (NEJM), all of which reaffirmed the safety and efficacy of drug-eluting stents.

Commenting on the editorial and articles describing results of two randomized clinical trials, PASSION and TYPHOON, the Company stated:

"We welcome the conclusion of The New England Journal of Medicine that drug-eluting stents are a safe and effective therapy, with lower retreatment rates than bare-metal stents. Patients who have suffered acute myocardial infarction (AMI, or a serious heart attack) are among the most complex and difficult groups to treat(i). In the PASSION trial, the lower rates of cardiac death and recurrent heart attack for the TAXUS® stent as compared to the bare-metal control stent -- and a particularly low retreatment rate of 5.3 percent -- reinforce the exceptional safety and efficacy of the TAXUS drug- eluting stent."

"[T]he data from these two trials indicate that drug-eluting stents can be used safely in the setting of primary PCI [percutaneous coronary intervention] and are likely to reduce the need for repeated revascularization," NEJM wrote in its editorial. The editorial also cautioned that "[i]t would be dangerous to conclude from these data that one drug-eluting stent is better than the other in primary PCI, since direct comparisons of the two stents for this indication are not available." The editorial noted that the retreatment rates for the TAXUS stent in the PASSION study and for the Cypher® stent in the TYPHOON study were "remarkably similar" at 5.3 percent and 5.6 percent, respectively. As indicated by the editor, differences in study design, definitions of endpoints and study conduct did not allow any side-by-side comparisons for the two different DES technologies in this clinical setting.

The PASSION trial showed that in AMI patients, the TAXUS stent achieved reductions in cardiac death (3.9 percent for the TAXUS stent versus 6.2 percent for the bare-metal control), target lesion revascularization, or retreatment rate (5.3 percent for the TAXUS stent versus 7.8 percent for bare metal) and reinfarction, or repeat heart attack (1.7 percent for the TAXUS stent versus 2.0 percent for bare metal). While not adequately powered to provide statistical significance, this study supports the safety and efficacy of the TAXUS stent technology in AMI. Boston Scientific is currently providing financial support for a randomized, controlled clinical trial designed to compare TAXUS stents to bare-metal stents in AMI patients. The 3,400-patient definitive HORIZONS AMI trial is powered to confirm the benefits of the TAXUS stent in AMI.

In the PASSION trial, the rate of angiographically confirmed stent thrombosis for the TAXUS stent (1.0 percent) was low and no different from the bare-metal control stent.

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, integration of acquired companies, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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(i) The TAXUS stent is not approved for treatment of AMI in the United States. It is approved for treatment of AMI in Europe.

SOURCE: Boston Scientific Corporation

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