Boston Scientific

Study Favors Drug-Eluting Stents Over Bare-Metal Stents in Key Patient Outcomes

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NATICK, Mass., Feb. 5 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed data from a study showing that drug- eluting stents (DES) have substantially lower rates of death, heart attack and re-intervention in real-world patients compared to bare-metal stents (BMS). The results of the study, "Comparison of Drug-Eluting Versus Bare-Metal Stents on Later Frequency of Acute Myocardial Infarction and Death," was published in the February 1 issue of the American Journal of Cardiology.

The observational study, which was conducted by the cardiology section of the Wake Forest University School of Medicine in Winston-Salem, N.C., compared clinical outcomes among 2,359 unselected patients receiving either BMS (n=1,126) or DES (n=1,233). At nine months, DES reduced the risk of acute myocardial infarction (AMI) and death by 23 percent and 32 percent, respectively (based on hazard ratios of 0.77 and 0.68). The rate of AMI, commonly referred to as a heart attack, was 3.7 percent in DES patients versus 4.7 percent in BMS patients, while the rate of death was 4.9 percent versus 7.1 percent, respectively ($p=0.03$). Furthermore, the rate of revascularization, or re-intervention, in DES was less than half that in BMS patients after nine months (6 percent versus 13.3 percent, $p<0.001$). Finally, there was a trend toward less stent thrombosis (clotting) in DES patients compared to BMS patients, though the rates were low in both groups (0.4 percent and 0.7 percent, respectively).

In an analysis of various patient subgroups, the use of DES was associated with lower risk of death across all populations, including those suffering from additional diseases such as diabetes, and those with complex lesions. In fact, the benefit of DES was most pronounced in higher-risk patients, such as those who experienced recent MI and those who received multiple stents.

"This study is worthy of note because it shows a significant advantage for drug-eluting stents over bare-metal stents with lower rates of death and heart attack as well as lower rates of re-intervention," said Paul LaViolette, Chief Operating Officer of Boston Scientific. "These findings are consistent with results shown in the TAXUS clinical program and suggest further that the benefit of drug-eluting stents may be even greater in real-world patients."

Data presented at a special panel on DES convened by the U.S. Food and Drug Administration (FDA) in December 2006 showed equivalent or lower rates of death and MI, and a nearly 50 percent reduction in the need for repeat procedures, for the TAXUS Stent versus BMS in 2,797 patients followed out to four years in four randomized clinical trials. Data on more than 7,000 patients with more complex lesions from the real-world ARRIVE registries predictably showed a slightly higher rate of death than in the simpler randomized patients. The Wake Forest results, suggesting lower death and MI with DES versus BMS in real-world complex lesions, further support the ARRIVE registry data and help counterbalance some earlier non-randomized comparisons that suggested slightly higher mortality with DES compared to historical BMS data in somewhat simpler lesions.

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 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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