Boston Scientific

Independent Meta-Analysis Confirms Safety and Efficacy of TAXUS Stent

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NATICK, Mass. and WASHINGTON, Oct. 23 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that an independent meta-analysis of more than 3,500 patients from five clinical trials, conducted by the Cardiovascular Research Foundation, confirmed the Company's own analysis that the TAXUS® paclitaxel-eluting coronary stent is safe and effective. The new analysis was presented by Gregg W. Stone, M.D., Vice Chairman of the Cardiovascular Research Foundation and Professor of Medicine, Columbia University Medical Center in New York, at a symposium hosted by Boston Scientific in conjunction with the eighteenth annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C.

The patient-level meta-analysis reported data on the TAXUS stent from the TAXUS I, II, IV, V and VI trials that studied 3,506 patients. A parallel patient-level meta-analysis was also performed on the Cypher® stent from the RAVEL, SIRIUS, E-SIRIUS AND C-SIRIUS trials that studied 1,748 patients, and will be presented in full by Dr. Stone on Tuesday.

The results presented today showed similar rates of freedom from stent thrombosis and similar rates of stent thrombosis beyond one year for both the TAXUS and Cypher stents.

For the TAXUS stent, the rate of freedom from stent thrombosis at up to four years was 98.7 percent (1.3 percent thrombosis rate), compared to a 99.1 percent rate of freedom from stent thrombosis (0.9 percent stent thrombosis rate) in the bare-metal control group. This meta-analysis showed a small but statistically significant (0.40 percent, p = 0.033) increase in the incidence of stent thrombosis after one year for the TAXUS stent as compared to the bare-metal control stent. However, there was no corresponding increase in death or myocardial infarction (MI).

Dr. Stone also presented data that showed for the Cypher stent, the rate of freedom from stent thrombosis over four years was 98.8 percent (1.2 percent stent thrombosis rate), compared to a 99.4 percent rate of freedom from stent thrombosis (0.6 percent stent thrombosis rate) in the bare-metal control group. This meta-analysis also showed a small but statistically significant (0.57 percent, p = 0.025) increase in the incidence of stent thrombosis after one year for the Cypher stent as compared to the bare-metal control stent. This is the first time a statistically significant increase in late stent thrombosis has been reported for the Cypher stent.

The results for up to four years follow-up also showed a trend toward a lower rate of all-cause death, as well as the combination all-cause death or Q-wave MI, for the TAXUS stent compared to its bare-metal control. Despite the 0.4 percent increase in late-stent thrombosis, the all-cause death rate at up to four years was 6.4 percent for the TAXUS stent compared to 7.0 percent for bare-metal (a statistically non-significant decrease). Similarly, the all-cause death or Q-wave MI rate showed a trend toward better outcomes for the TAXUS stent at 7.6 percent compared to 8.1 percent for bare-metal (a statistically non-significant decrease).

"It is now fully apparent that the small increase in late stent thrombosis that we previously reported is actually found in both drug-eluting stents," said Dr. Donald S. Baim, the Chief Medical and Scientific Officer for Boston Scientific. "Importantly, the TAXUS paclitaxel-eluting stent continues at four-year follow-up to show the same or lower risk of death or MI as bare-metal, and a 50 percent lower need for repeat procedures. In net, it clearly remains a safe and effective therapy."

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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