Boston Scientific

OLYMPIA Phase I Registry Demonstrates Safety and Performance of TAXUS® Liberte™ Stent System in Complex Patients and Lesions

NATICK, Mass. and BARCELONA, Spain, Sept. 5 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced six-month results from Phase I of its global TAXUS OLYMPIA registry, supporting the safety and performance of the TAXUS® Liberte™ coronary stent system in real-world patients. The results were announced at the European Society of Cardiology/World Congress of Cardiology 2006 in Barcelona, Spain. TAXUS Liberte is currently pending approval by the U.S. Food and Drug Administration and is not for sale in the United States.

Phase I of the global OLYMPIA registry included 529 patients from seven countries in which TAXUS Liberte has been approved. The Phase I enrollment consisted of diverse and high-risk populations, reflecting complex usage patterns in "real world" clinical practices. A majority of patients exhibited complex lesions or clinical characteristics, including, multi-vessel disease (49.1 percent), prior myocardial infarction (45.9 percent), left anterior descending (LAD) lesions (54.0 percent), small vessels (9.0 percent), long lesions (18.9 percent) and diabetes (49.9 percent).

"The OLYMPIA Phase I six-month data are very impressive, especially considering the high degree of patient and procedural complexity across a broad range of real world cases," said Waqar H. Ahmed, M.D., M.S., FACC, at King Fahed Armed Forces Hospital in Jeddah, Saudi Arabia, and the Principal Investigator for the first Phase of the OLYMPIA registry. "The data show consistency with results from other TAXUS clinical trials and registries, further supporting the strong performance of the TAXUS Liberte coronary stent system."

OLYMPIA Phase I six-month findings demonstrated an overall TAXUS Liberte related cardiac event rate of 2.3 percent, including cardiac death (0.8 percent), myocardial infarction (1.3 percent), and TAXUS Liberte related re- intervention of the target vessel (1.3 percent). The OLYMPIA Phase I registry reported a stent thrombosis rate of 1.5 percent, including 1.1 percent at 0-30 days and 0.4 percent from 30-180 days. This low rate of thrombosis is consistent with safety data from other DES registries. Non-compliance with antiplatelet therapy was the strongest risk factor for thrombosis and was observed for half of the total stent thrombosis cases.

In the diabetic subset (261 patients), OLYMPIA reported low rates of overall TAXUS Liberte related cardiac events (1.5 percent), cardiac death (0.4 percent), myocardial infarction (0.8 percent), TAXUS Liberte related re- interventions (1.1 percent) and stent thrombosis (1.1 percent). Each of these outcomes for the high-risk diabetic patient group was lower than the rates for the overall population.

"Phase I of OLYMPIA shows excellent outcomes with TAXUS Liberte in patient subsets considered high risk for bare metal stenting, including diabetics, small vessels, long lesions and multiple stents," said Jeff Goodman, President of Boston Scientific International. "The results build on the impressive body of positive data from the TAXUS clinical program, especially in complex diabetic patients. Our second-generation platform -- TAXUS Liberte -- offers exceptional deliverability backed by the confidence of proven outcomes in complex lesions."

Phase I of the OLYMPIA registry met its primary endpoint of TAXUS Liberte stent-related cardiac events at 30 days post implant. In addition, all secondary endpoints were met including; stent-related cardiac events at six months, target vessel-related cardiac events at 30 days and six months, and angiographic and technical success.

The global, prospective OLYMPIA registry plans to enroll up to 27,000 patients in multiple phases from more than 500 centers in 70 countries and is designed to analyze real-world clinical outcomes data for Boston Scientific's next-generation TAXUS Liberte paclitaxel-eluting stent system in the treatment of patients with coronary artery disease.

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, 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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