Boston Scientific

World's Largest Drug-Eluting Stent Registry Completes European and Intercontinental Enrollment Phases

NATICK, Mass., May 14 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has completed enrollment in the European and Intercontinental phases (II and III) of its TAXUS OLYMPIA registry, bringing the total number of current patients to more than 23,000. The registry is designed to evaluate the safety and performance of the Company's second-generation drug-eluting coronary stent (DES), TAXUS® Liberte™(1), in a real-world setting. OLYMPIA is the world's largest DES registry and plans to enroll at least 27,000 patients treated for complex coronary lesions at more than 400 centers worldwide.

"The size of the OLYMPIA registry is truly unprecedented in the DES field and will yield invaluable real-world information to the benefit of interventional cardiologists and those patients who suffer from cardiovascular disease," said Martyn Thomas, M.D., F.R.C.P., Director of Invasive Cardiology, Kings College Hospital, London, and one of the coordinating investigators of the registry. "We expect the results from this registry to remain consistent with the safety and efficacy results we've seen in previous clinical trials featuring the TAXUS stent system in complex patients with complex lesions."

The multi-center, prospective, observational OLYMPIA registry will evaluate a variety of safety and performance measures, including the rate of repeat procedures (target lesion revascularization, or TLR) and major adverse cardiac events. Additionally, sub-analyses on complex patient groups such as diabetics, patients with multi-vessel disease, in-stent restenosis (re-blockages) or a prior history of heart attack will be performed.

The OLYMPIA registry is enrolling patients in multiple phases, corresponding to the commercial introduction of the TAXUS Liberte stent system in different regions of the world. The initial, transitional phase enrolled 529 patients from a limited number of international markets in which TAXUS Liberte was commercially available. The Phase I enrollment consisted of diverse and high-risk populations (including 50 percent diabetics, 49 percent multi-vessel disease, 40 percent small vessels, and 48 percent complex lesions defined as B2/C), reflecting complex usage patterns in "real-world" clinical practices. Twelve-month results from OLYMPIA Phase I were announced at the 2006 Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in Washington, D.C. The results demonstrated an overall TAXUS Liberte stent-related cardiac event rate of 3.7 percent, including myocardial infarction (1.4 percent), and TAXUS Liberte stent-related re-intervention of the target vessel (1.9 percent), with an overall cardiac death rate of 1.5 percent.

The next and final phase of the registry (IV) will enroll U.S. patients, following regulatory approval. Data collected for the OLYMPIA registry are being uniformly reported through a web-based data capture system, and all major clinical events are regularly reviewed and adjudicated by an independent Clinical Event Committee of interventional cardiologists or an Independent Medical Reviewer.

About the TAXUS Liberte Stent

The TAXUS Liberte coronary stent system is the second generation to Boston Scientific's market-leading paclitaxel-eluting coronary stent system, TAXUS® Express2™. TAXUS Liberte is currently the market leader in Europe and other international markets where it is available. TAXUS Liberte is pending PMA approval and is not available for sale in the U.S.

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.

(1) The TAXUS Liberte Stent system is currently only available in Europe, Asia Pacific, and Latin America.

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