

World's Largest Drug-Eluting Stent Registry Reaches Halfway Point in Enrollment

PRNewswire-FirstCall
NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., Aug. 31 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) announced today that enrollment has exceeded 13,000 patients in the TAXUS OLYMPIA registry, 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 up to 27,000 patients treated for complex coronary lesions, at more than 500 centers worldwide.

"The advent of the TAXUS Liberte stent system has raised the bar in terms of the performance of DES, since it provides physicians with the increased flexibility and deliverability they need to treat complex coronary artery blockages," said Martyn Thomas, M.D., F.E.S.C., Director of Invasive Cardiology, Kings College Hospital, London, UK and one of the coordinating investigators of the registry. "We look forward to seeing how these improved features will be reflected in the near- and long-term clinical outcomes to be obtained from the OLYMPIA registry."

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), major adverse cardiac events such as heart attack (myocardial infarction) and death, and in-stent thrombosis. Additionally, sub-analyses on complex patient groups such as diabetics, patients with multi-vessel disease, in-stent re-blockages (restenosis) or a prior history of heart attack will be performed.

"The OLYMPIA registry is the first to specifically document the real-world outcomes in patients treated with a next-generation DES such as Boston Scientific's TAXUS Liberte stent," said Jeff Goodman, President, Boston Scientific International. "OLYMPIA will provide some of the most comprehensive real-world data for DES use in treating coronary artery disease. We expect the results will further support the safety and performance of the TAXUS Liberte stent system in complex lesions and complex patients."

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 is already commercially available. The six-month results from Phase I were presented at the SOLACI 2006 Congress in Porto Alegre, Brazil and showed a low overall TAXUS-related major cardiac event rate of 2.3 percent. Additional data will be presented at the European Society of Cardiology/World Congress of Cardiology 2006 in Barcelona, Spain.

"Phase I showed that 50 percent of the patients included were diabetic," stated Waqar H. Ahmed, M.D., M.S., FACC, at King Fahed Armed Forces Hospital in Jeddah, Saudi Arabia, coordinating investigator of Phase I and also co-chairing Phase II with Oscar A. Mendiz, M.D., at Fundacion Favaloro in Buenos Aires, Argentina. "We are excited to have the TAXUS Liberte stent system available to treat our patients," said Dr. Ahmed. "It is a significant advance in stent design and deliverability and may be more effective than other drug eluting stents in patients with more complex lesions."

Phases II and III, for which enrollment is currently ongoing, involve up to 24,000 patients from Intercontinental and European markets. The final phase will enroll U.S. patients. 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™. The Liberte stent features the Veriflex™ stent design, a highly flexible cell geometry with thin struts and uniform cell distribution. This new platform has been designed for uniform drug delivery and to offer improved deliverability and conformability in challenging anatomy. 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.

CONTACT: Milan Kofol
508-650-8569
Investor Relations
Boston Scientific Corporation

Paul Donovan
508-650-8541
Media Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Milan Kofol, +1-508-650-8569, or Paul Donovan, +1-508-650-8541,
both of Boston Scientific Corporation

Web site: <http://www.bostonscientific.com/>

<https://news.bostonscientific.com/largest-drug-eluting-stent-registry-halfway-enrollment>