Boston Scientific

Boston Scientific Announces Enrollment of First Patient in Post-Approval Study for TAXUS Liberte Stent

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NATICK, Mass., Jan. 4 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has enrolled the first patient in its TAXUS Liberte post-approval study. The study is designed to evaluate real-world clinical outcomes data for the TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System in combination with a dual antiplatelet therapy drug regimen that includes aspirin and Effient®, a new antiplatelet medication. Co-sponsors of the study include Eli Lilly and Company and Daiichi Sankyo, Inc., manufacturers of Effient, which was recently approved by the U.S. Food and Drug Administration (FDA). The first patient was enrolled by Joel Cohn, M.D., F.A.C.C., at the Ingham Regional Medical Center in Lansing, Michigan.

TAXUS Liberte is a prospective surveillance study that will enroll approximately 4,200 consecutive patients at up to 65 U.S. sites. The study will evaluate clinical outcomes in a broad range of patients with coronary artery disease who receive a TAXUS Liberte Stent followed by the use of aspirin and Effient(1). The primary endpoint of the study is the rate of cardiac death or myocardial infarction (MI) at 12 months. Secondary endpoints will be analyzed out to five years and include rates of stent thrombosis using the Academic Research Consortium (ARC) definition, target vessel failure (TVF), target vessel revascularization (TVR), MI, bleeding events and stroke.

"The TAXUS Liberte Stent has been studied extensively in the ATLAS and OLYMPIA clinical programs with impressive results," said Keith D. Dawkins, M.D., Senior Vice President and Associate Chief Medical Officer at Boston Scientific. "The TAXUS Liberte post-approval study will allow us to further assess the second-generation TAXUS Liberte Stent -- along with the use of Effient and aspirin -- in a variety of complex lesions."

Boston Scientific plans to contribute data on the first 1,524 eligible patients from the TAXUS Liberte study to the DAPT Study, a landmark collaboration among the FDA, drug and device manufacturers, and the Harvard Clinical Research Institute (HCRI). This four-year public health study will investigate the appropriate duration of dual antiplatelet therapy following drug-eluting stent implantation. HCRI is responsible for the scientific management and independent analysis of the overall study.

"Boston Scientific is proud to participate in this important public health study," added Dawkins. "The value of antiplatelet drugs in reducing events such as myocardial infarction and stent thrombosis after stent implantation has been demonstrated but the optimal duration of this therapy is less clear. The results of the DAPT Study should provide new insights into the use of dual antiplatelet medication with drug-eluting stents and help establish more definitive guidelines for clinical practice."

The TAXUS Liberte Stent employs an advanced stent design for more consistent drug distribution and greater stent deliverability to the target lesion. When compared to the TAXUS Express® Stent, Boston Scientific's TAXUS Liberte Stent features a hybrid cell design with more uniform stent architecture, a 27 percent reduction in strut thickness and superior results when treating patients with small diameter vessels or long lesions, as demonstrated in the TAXUS ATLAS Small Vessel and Long Lesion studies.

The primary investigators of the TAXUS Liberte study are Kirk Garratt, M.D., from Lenox Hill Hospital in New York, and David P. Lee, M.D., from Stanford University Medical Center.

Effient® is a registered trademark of Eli Lilly and Company.

The TAXUS Liberte Stent received CE Mark approval in 2005, U.S. FDA approval in 2008 and Japanese approval in 2009.

About the DAPT Study

The DAPT Study is an independently managed, large-scale study designed to investigate the benefits of 12 versus 30 months of dual antiplatelet therapy (the combination of aspirin and a second anti-clotting medication to reduce the risk of blood clots) to protect patients from stent thrombosis and major adverse cardiovascular and cerebrovascular events (MACCE) following the implantation of drug-eluting coronary stents.

The DAPT Study concept was developed by a group of major stent manufacturers and the manufacturers of thienopyridine/antiplatelet medications who came together to address an FDA request for this post-market study. The Harvard Clinical Research Institute is responsible for the scientific conduct and independent analysis of the overall study.

About Boston Scientific

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: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding clinical trials, product performance and patient outcomes. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A - *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A - *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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(1) Effient® is approved for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndromes (ACS) who are managed with percutaneous coronary intervention (PCI).

SOURCE: Boston Scientific Corporation

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