Boston Scientific

Boston Scientific Receives FDA Approval For Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Advanced Stent Technology to Launch Immediately in the United States

NATICK, Mass., Nov. 25, 2013 /PRNewswire/ -- Continuing to advance leading drug-eluting stent (DES) technology, Boston Scientific Corporation (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System, the company's next-generation durable polymer drug-eluting stent (DES).

The technology is available immediately in the U.S., with the first implantation scheduled to be performed by Martin Leon, M.D., director, Center for Interventional Vascular Therapy at Columbia University Medical Center / New York-Presbyterian Hospital, New York City.

"It's very rewarding, professionally, to be the first to provide this new DES therapy to my patients," said Leon. "Perhaps the most impressive benefit of the Promus PREMIER Stent System is its unparalleled visibility, which combined with enhanced customized stent architecture, leads to an advance in currently available durable polymer DES."

The Promus PREMIER Stent System offers physicians improved DES performance in treating patients with coronary artery disease, and features unique customized platinum chromium alloy stent architecture, the market-leading Everolimus drug with a biocompatible, fluorinated co-polymer and an enhanced stent delivery system. Images of the Promus PREMIER Stent System are available for download here.

"After using this product for nearly a year, I am confident that Boston Scientific has advanced thin-strut technology," said John Ormiston, M.D., Mercy Angiography Auckland Hospital, Auckland, New Zealand. "The customized platinum chromium stent architecture maintains excellent radial strength and flexibility along with optimal radiopacity, while offering improved longitudinal strength. In addition, the enhanced stent delivery system contributes to superior stent deliverability."

Coronary artery disease is a narrowing of blood vessels that supply blood and oxygen to the heart. Patients with coronary artery disease may experience pain, shortness of breath and fatigue. They may also be at risk for a heart attack. One treatment option is the placement of a stent in the artery to help keep it open and allow the blood to flow more freely.

The Promus PREMIER Stent System was developed with extensive input from interventional cardiologists and is designed to provide best in class acute and clinical outcomes. It features unparalleled visibility, low recoil, exceptional radial strength and fracture resistance, while improving axial strength and deliverability. An enhanced low-profile delivery system features a shorter, more visible tip, a dual-layer balloon and a Bi-Segment™ inner lumen catheter designed to facilitate precise stent delivery across challenging lesions.

The Everolimus drug and PVDF-HFP stent coating have been studied in multiple randomized clinical trials demonstrating long-term safety and efficacy. The PLATINUM Clinical Trial Program demonstrated exceptional safety and efficacy of the PROMUS Element™ Stent System (Platinum Chromium Everolimus-Eluting stent) when compared to the Xience V™ Stent (Cobalt Chromium Everolimus-Eluting stent), including a significant reduction in bail-out stenting, providing an average of $116 in savings per procedure.[1] Further review of the Platinum data demonstrated that the PROMUS Element Stent System is associated with significantly less vessel straightening in severely angulated lesions and resulted in numerically lower clinical event rates out to three years.

"The Promus PREMIER Stent System reflects our commitment to DES technology and to providing interventional cardiologists with the most complete portfolio of clinical solutions," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "Through ongoing collaboration with physicians, we expect to continue to innovate and build on our industry-leading platinum chromium platform."

The Promus PREMIER Stent System is offered in a matrix of 94 sizes, ranging in diameter from 2.25 mm to 4.00 mm and lengths of 8 mm to 38 mm on both Monorail® and Over-the-Wire catheter platforms. This provides physicians and their patients with a broad range of options designed to best suit their needs. The company received CE Mark approval for the Promus PREMIER Stent System in February, 2013.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 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, markets for our products, our business plans, statements regarding new product launches and launch cadence, regulatory approvals, clinical trials, product performance and impact, and competitive offerings. 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.

1. Hale C, Stern S, Kansal A, et al. Adapted from: Economic Analysis of Stent Platforms: Cost-Effectiveness of the Platinum Chromium PROMUS Element™ compared to Cobalt Chromium PROMUS™/Xience V™ Everolimus-Eluting Stents. Presented at the International Society of Pharmaeconomics and Outcomes Research (ISPOR) 2013 Meeting.

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