Boston Scientific

Boston Scientific's Promus Element™ Platinum Chromium Stent System Demonstrates Comparable Safety And Effectiveness Outcomes Versus Leading Drug-Eluting Stent In Platinum Workhorse Trial

Reduction of geographic miss and bail-out stenting observed with highly visible PROMUS Element Stent

NATICK, Mass. and NEW ORLEANS, April 4, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced 12-month results from the pivotal PLATINUM Workhorse trial comparing the safety and effectiveness of the PROMUS Element™ Everolimus-Eluting Platinum Chromium (PtCr) Coronary Stent System to the PROMUS® Everolimus-Eluting Coronary Stent System. The trial demonstrated the clinical non-inferiority of the PROMUS Element Stent in comparison to the PROMUS Stent in treating *de novo* coronary artery lesions while showing a procedural benefit of reduced rates of unplanned (bail-out or emergency) stenting.

Results were presented during a late-breaking trial session at the American College of Cardiology Annual Scientific Sessions by Gregg W. Stone, M.D., Professor of Medicine and Director of Research and Education at the Center for Interventional Vascular Therapy at Columbia University Medical Center/New York-Presbyterian Hospital and Global Principal Investigator of the trial. Results were also published concurrently in the online version of the Journal of American College of Cardiology (JACC) and will be available in the April 19 print edition.

"The PROMUS Element Platinum Chromium Stent met the primary non-inferiority endpoint of target lesion failure at one year compared to the PROMUS Stent while demonstrating excellent safety and effectiveness with low rates of cardiac death, myocardial infarction, stent thrombosis and revascularization," said Dr. Stone. "The remarkably low rates of stent thrombosis and target lesion revascularization at one year confirm the successful transfer of the favorable outcomes associated with everolimus to the novel platinum chromium stent design."

The primary endpoint of non-inferiority for the PROMUS Element Stent compared to the PROMUS Stent was met with a 12-month target lesion failure (TLF) rate in the per protocol population of 3.4 percent versus 2.9 percent, respectively (pNI=0.001). No statistically significant differences in TLF components were observed between the two stents. In the intention-to-treat population, TLF (3.5 percent vs. 3.2 percent, p=0.72), cardiac death related to the target vessel (0.8 percent vs. 0.4 percent, p=0.51), myocardial infarction (MI) related to the target vessel (0.8 percent vs. 1.6 percent, p=0.14) and ischemia-driven target lesion revascularization (TLR, 1.9 percent vs. 1.9 percent, p=0.96) were all similar. Low rates of target vessel revascularization (TVR, 2.7 percent vs. 2.9 percent, p=0.83) and stent thrombosis (ARC definite/probable, 0.4 percent vs. 0.4 percent, p=0.99) were also observed at 12 months for the PROMUS Element and PROMUS Stents.

Both stents achieved high rates of technical success (99.4 percent for PROMUS Element vs. 98.8 percent for PROMUS, p=0.14) indicating successful delivery and deployment of the stent to the target vessel. The PROMUS Element Stent achieved a significant reduction in unplanned (bail-out or emergency) stenting (5.9 percent vs. 9.8 percent, p=0.004), including a significantly lower rate of inadequate lesion coverage (1.4 percent vs. 3.4 percent, p=0.01). These clinical observations are consistent with the results of comparative bench and animal studies, which have demonstrated the enhanced visibility of the PROMUS Element Stent relative to the PROMUS Stent.

"We are extremely pleased that the highly opaque platinum chromium alloy PROMUS Element Stent significantly reduced both inadequate lesion coverage ('geographic miss') and the need for unplanned (bail-out) stenting," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "The PROMUS Element Stent offers interventional cardiologists a true next-generation stenting option for patients with coronary artery disease."

The PROMUS Element Stent System received CE Mark approval and was launched in Europe and other international markets in 2009. It features an innovative PtCr alloy and new stent design to offer greater strength, enhanced deliverability and exceptional visibility. The thin-strut stent is designed for improved conformability, minimal recoil, and uniform lesion coverage and drug distribution. The advanced low-profile delivery system facilitates precise delivery of the stent across challenging lesions.

The PLATINUM clinical program is evaluating the safety and effectiveness of the PROMUS Element Stent in five multi-center studies totaling more than 1,800 patients, including single-arm studies evaluating small vessels, long lesions, pharmacokinetics, and quantitative coronary angiography and intravascular ultrasound data. PLATINUM Workhorse is a global, randomized, pivotal controlled trial designed to support U.S. Food and Drug Administration (FDA) approval of the PROMUS Element Stent System. The trial enrolled 1,530 patients with up to two *de novo* lesions at 132 sites worldwide, and completed enrollment in September 2009.

The PERSEUS clinical program compared the ION (TAXUS Element) Stent to prior-generation Boston Scientific

stents in more than 1,600 patients in two parallel trials at 90 centers worldwide. The PERSEUS Workhorse trial reported 12-month results in March 2010, demonstrating positive safety and efficacy outcomes in workhorse lesions for the ION Stent System compared to the TAXUS® Express2® Stent System.

The Company anticipates FDA approval for the PROMUS Element Stent in mid 2012. In the U.S., the PROMUS Element Stent is an investigational device, limited by applicable law to investigational use only and not available for sale.

In the U.S., the TAXUS Element Stent System will be commercialized as the ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System. In the U.S., the ION Stent System is an investigational device, limited by applicable law to investigational use only and not available for sale. The Company expects to launch the ION Stent System in the United States by mid-2011. The TAXUS Element Stent System received CE Mark approval in May 2010.

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 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, statements regarding new product launches and launch cadence, regulatory approvals, clinical trials, product performance, and impact on the coronary stent market 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.

CONTACT: Erik Kopp
508-650-8660 (office)
Media Relations
Boston Scientific
Corporation
erik.kopp@bsci.com

Sean Wirtjes
508-652-5305 (office)
Investor Relations
Boston Scientific
Corporation
investor_relations@bsci.com

SOURCE Boston Scientific Corporation

---

https://news.bostonscientific.com/news-releases?item=59315