

Landmark Analysis of Year Two Data From PLATINUM Workhorse Trial Demonstrates Superior Efficacy of PROMUS Element™ Platinum Chromium Stent Compared to PROMUS® (Xience V®) Stent

NATICK, Mass. and CHICAGO, March 25, 2012 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) announces two-year follow-up data 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® (Xience V®) Everolimus-Eluting Coronary Stent System. The outcomes reported at 12 months for the PROMUS Element Stent and the PROMUS (Xience V) Stent remained comparable at two years. However, an additional landmark analysis of outcomes from year one to year two demonstrated superior efficacy of the PROMUS Element Stent as compared to the PROMUS (Xience V) Stent during this 12-month period of follow-up. Results were presented 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.

"The PROMUS Element Platinum Chromium Stent continues to demonstrate excellent safety and effectiveness with low rates of cardiac death, myocardial infarction, stent thrombosis and repeat revascularization," said Dr. Stone. "These long-term results confirm that this device is an effective option for treating patients with coronary artery disease. Of particular note, a statistically significant reduction in recurrent ischemia requiring repeat revascularization procedures was present between the first and second year with the platinum chromium stent. This finding is potentially important, but must be confirmed by longer-term follow-up."

The trial reported a two-year target lesion failure (TLF) rate of 4.4 percent for the PROMUS Element Stent compared to 5.8 percent for the PROMUS (Xience V) Stent ($p=0.32$). The PROMUS Element Stent demonstrated numerically lower but not statistically different event rates than the PROMUS (Xience V) Stent in TLF components at two years, including cardiac death related to the target vessel (0.9 percent vs. 1.1 percent, respectively, $p=0.98$), myocardial infarction (MI) related to the target vessel (1.2 percent vs. 2.1 percent, $p=0.28$) and ischemia-driven target lesion revascularization (TLR, 2.4 percent vs. 4.0 percent, $p=0.12$). Low rates of target vessel revascularization (TVR, 4.2 percent vs. 5.6 percent, $p=0.30$) and stent thrombosis (ARC definite/probable, 0.5 percent vs. 0.7 percent, $p=0.99$) were observed at two years for both stents.

In a landmark analysis of event rates from year one to year two, the PROMUS Element Stent demonstrated statistically significant differences in TLF (1.2 percent vs. 3.0 percent, $p=0.04$, 56 percent relative reduction), and TLR (0.7 percent vs. 2.2 percent, $p=0.02$, 67 percent relative reduction) compared to the PROMUS (Xience V) Stent, showing superior efficacy of the PROMUS Element Stent from 12 months to two years.

Trial results also confirmed a previously reported significant reduction in unplanned (bail-out or emergency) stenting with the PROMUS Element Stent (5.9 percent vs. 9.8 percent, $p=0.004$), including a significantly lower rate of inadequate lesion coverage or 'geographic miss' (1.4 percent vs. 3.4 percent, $p=0.01$). These clinical observations reflect the results of comparative bench and animal studies, which have demonstrated the enhanced visibility and deliverability of the PROMUS Element Stent relative to the PROMUS (Xience V) Stent.

The prospective, multicenter, randomized PLATINUM Workhorse trial enrolled 1,530 patients with up to two *de novo* lesions at 132 clinical sites worldwide. The trial met its primary endpoint of 12-month target lesion failure demonstrating non-inferiority for the platinum chromium PROMUS Element Stent compared to the cobalt chromium PROMUS (Xience V) Stent. The comprehensive PLATINUM clinical program is evaluating the safety and effectiveness of the PROMUS Element Stent in six multi-center studies totaling more than 1,900 patients, including single-arm studies evaluating small vessels, long lesions, pharmacokinetics, and quantitative coronary angiography and intravascular ultrasound data.

"With its exceptional deliverability and visibility, the PROMUS Element Stent offers interventional cardiologists a true next-generation stenting option for patients with coronary artery disease. We are excited by these data from the landmark analysis, which exhibited superior efficacy of the PROMUS Element Stent," said Kevin Ballinger, President of the Cardiology Division at Boston Scientific. "We are pleased that the internally manufactured PROMUS Element Stent platform is now approved in every major market worldwide and continues to meet our high expectations."

The PROMUS Element Stent, used in the PROMUS Element Stent System and the PROMUS Element™ Plus Stent System, employs a proprietary PtCr alloy designed specifically for coronary stenting, which enables enhanced visibility, less recoil, excellent conformability and higher radial strength. The PROMUS Element Plus Stent System employs an advanced low-profile delivery system to facilitate precise delivery of the stent across challenging lesions.

The Company received CE Mark approval for the PROMUS Element Stent System in 2009 and for the PROMUS Element Plus Stent System in 2011. In the U.S., the PROMUS Element Plus Stent System was approved by the Food and Drug Administration in 2011.

Xience V is a trademark of the Abbott Laboratories group of companies. The PROMUS Stent is a private-labeled Xience V

Stent manufactured by Abbott and distributed by Boston Scientific.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that 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 clinical trials, product performance and effects, clinical outcomes, 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:

Eric Olson
336-293-4393 (office)
Media Relations
Boston Scientific Corporation
eric.olson@bsci.com

Sean Findlen
617-520-7268 (office)
Media Relations
Weber Shandwick
sfindlen@webershandwick.com

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

SOURCE Boston Scientific Corporation

<https://news.bostonscientific.com/platinum-workhorse-trial-two-year-results?l=25&o=1150>