

## **PERSEUS Trial Results Demonstrate Positive Safety and Efficacy Outcomes for Boston Scientific's Novel Platinum Chromium TAXUS® Element™ Stent System**

NATICK, Mass. and ATLANTA, March 15 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced 12-month results from its PERSEUS clinical program that demonstrated positive safety and efficacy outcomes in workhorse lesions for the platinum chromium TAXUS® Element™ Paclitaxel-Eluting Stent System compared to the TAXUS® Express2™ Paclitaxel-Eluting Stent System. The results also reported a similar safety profile and statistically superior efficacy outcomes in small vessels for the TAXUS Element Stent compared to a historical control group of patients receiving the Express® bare-metal stent.

Analysis of the data was presented at the American College of Cardiology Annual Scientific Sessions during a late-breaking trial session by Dean Kereiakes, M.D., Medical Director at The Christ Hospital Heart and Vascular Center and The Lindner Research Center in Cincinnati and the Principal Investigator for the PERSEUS clinical program.

"We are very encouraged by the one-year data demonstrating positive safety and efficacy outcomes for the TAXUS Element Stent and its innovative platinum chromium alloy," said Dr. Kereiakes. "In my experience, the TAXUS Element Stent offers increased flexibility, visibility and deliverability compared with currently available products. The PERSEUS data confirm that the proven TAXUS drug and polymer combination has been successfully transferred to the Element platform with excellent performance and comparable safety."

The TAXUS Element Stent is designed specifically for coronary stenting. The novel stent architecture and proprietary platinum chromium alloy combine to offer greater radial strength and flexibility. The stent architecture helps create consistent lesion coverage and drug distribution while improving deliverability, which is enhanced by an advanced catheter delivery system. The higher density alloy provides superior visibility and reduced recoil while permitting thinner struts compared to prior-generation stents(1).

"Boston Scientific continues to build on its legacy of drug-eluting stent leadership through the development of our third-generation TAXUS Element Stent System," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "In addition, we remain the only company to offer customers a choice of two drugs."

The PERSEUS clinical program compares the TAXUS Element Stent to prior-generation stents in more than 1,600 patients in two parallel trials at 90 centers worldwide.

### **Workhorse trial**

The pivotal PERSEUS Workhorse trial is evaluating the safety and efficacy of the TAXUS Element Stent compared to Boston Scientific's first-generation TAXUS Express Stent in 1,262 patients with *de novo* lesions.

The prospective, randomized (3:1) trial met its primary endpoint of non-inferiority for target lesion failure(2) (TLF) at 12 months with rates of 5.6 percent for the TAXUS Element Stent and 6.1 percent for the TAXUS Express Stent(3). The secondary endpoint of in-segment percent diameter stenosis at nine months as measured by quantitative coronary angiography (QCA) was also met.

The Workhorse results also demonstrated similar safety for the TAXUS Element Stent as demonstrated by

low rates of Major Adverse Cardiac Events (MACE) and stent thrombosis. All components of MACE, including cardiac death, myocardial infarction (MI) and target vessel revascularization (TVR) were similar to the TAXUS Express Stent control. A numerically lower rate of non-Q-wave MI for the TAXUS Element Stent resulted in lower overall MI (2.2 vs. 2.9 percent,  $p=0.48$ ). Stent thrombosis rates using the Academic Research Coalition (ARC) definite/probable definition were statistically similar for the TAXUS Element Stent and the TAXUS Express Stent (0.4 and 0.3 percent,  $p>0.99$ ).

### **Small Vessel trial**

Results were also presented from the PERSEUS Small Vessel trial, a single-arm study which compares the TAXUS Element Stent in 224 patients with small vessels ( $> \text{ or } = 2.25 \text{ to } < 2.75 \text{ mm}$  in diameter and  $< \text{ or } = 20 \text{ mm}$  in length) to a matched historical control group of 125 patients treated with the Express bare-metal stent. The trial met its primary endpoint of superiority for in-stent late loss at nine months with unadjusted values of 0.38 mm for the TAXUS Element Stent and 0.80 mm for the Express Stent ( $p<0.001$ ). The trial also met its secondary endpoint of superiority for TLF at 12 months, showing a statistically significant reduction with an unadjusted rate of 7.3 percent for the TAXUS Element Stent compared to a pre-specified performance goal of 19.5 percent ( $p<0.001$ ) based on historical outcomes for the control stent. The propensity-adjusted MACE rates were significantly lower for the TAXUS Element Stent compared to the bare-metal control stent (10.5 vs. 30.4 percent,  $p=0.002$ ), showing a safety benefit for the TAXUS Element Stent. Stent thrombosis rates using the ARC definite/probable definition were comparable for the TAXUS Element Stent and Express Stent (0.3 vs. 0.6 percent,  $p=0.65$ ).

"The PERSEUS trials build on the extensive data from the TAXUS clinical program and extend the consistent outcomes seen in the TAXUS trials to the novel Element Stent platform," said Louis Cannon, M.D., of the Cardiac and Vascular Research Center of Northern Michigan in Petoskey, Michigan and the trial's Co-Principal Investigator. "With the positive outcomes of the TAXUS Element Stent in workhorse lesions and the superior efficacy data in small vessels, platinum chromium promises to offer significant advantages in acute performance with no compromise to safety."

Clinical data from the PERSEUS trials will support regulatory approval of the TAXUS Element Paclitaxel-Eluting Stent System in Europe, the U.S. and Japan. The Company is evaluating its PROMUS® Element™ Everolimus-Eluting Stent System in the PLATINUM clinical trial, which completed enrollment of 1,531 patients in September 2009 at 133 sites worldwide. PLATINUM is a randomized, controlled, pivotal trial designed to support U.S. and Japanese approval of the PROMUS Element Stent System. Results are expected to be presented in early 2011.

The Company received CE Mark approval for the PROMUS Element Stent System in October 2009 and expects CE Mark approval for the TAXUS Element Stent System in the second quarter of this year. In the U.S., the Company expects FDA approval for the TAXUS Element Stent System in the middle of next year and for the PROMUS Element Stent System in the middle of 2012. In Japan, the Company expects approval for the TAXUS Element Stent System in late 2011 or early 2012 and for the PROMUS Element Stent System in the middle of 2012.

The TAXUS Element Stent and the PROMUS Element Stent are investigational devices in the U.S. and are limited by applicable law to investigational use only and are not available for sale.

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](http://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 our product performance, clinical outcomes, regulatory approval of our products, and our growth strategy. 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) Based on bench testing. Data on file with Boston Scientific.

(2) TLF is defined as ischemia-driven target lesion revascularization (TLR) or myocardial infarction/cardiac death related to the target vessel. Complete trial design at Allocco et al., *Trials* 2010, 11:1.

(3) Bayesian probability of non-inferiority = 99.96 percent.

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