# Boston Scientific ION<sup>™</sup> Platinum Chromium Stent System Demonstrates Strong Performance in Analysis of PERSEUS and TAXUS ATLAS Clinical Trial Data

## Lower event rates for new alloy and stent design versus older drug-eluting stent model

NATICK, Mass. and NEW ORLEANS, April 3, 2011 /<u>PRNewswire</u>/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from a pooled patient-level analysis of its PERSEUS and TAXUS ATLAS clinical trial data, demonstrating differences in safety and efficacy outcomes favoring the next-generation ION<sup>™</sup> Platinum Chromium (PtCr) Paclitaxel-Eluting Stent System (TAXUS® Element<sup>™</sup>) compared to the currently available TAXUS® Liberte® Paclitaxel-Eluting Stent System. Results were presented at the American College of Cardiology Annual Scientific Sessions by Dean Kereiakes, M.D., Medical Director at The Christ Hospital Heart and Vascular Center and The Lindner Research Center in Cincinnati and Principal Investigator for the PERSEUS clinical program.

"Although the ION and TAXUS Liberte Stents employ the same drug and polymer, the ION Stent demonstrated significantly lower rates of major adverse cardiac events (MACE), target lesion failure (TLF) and myocardial infarction (MI) in this case-matched analysis of nearly 2,300 patients," said Dr. Kereiakes. "This study demonstrates that alloy composition, stent design and strut thickness may influence angiographic and clinical outcomes following drug-eluting stent deployment."

The study compared pooled patient-level data from 2,298 patients enrolled in the PERSEUS (ION Stent) and TAXUS ATLAS (TAXUS Liberte Stent) trials. Propensity score matching was performed to adjust for differences in patient and lesion characteristics between the groups, and clinical follow-up was conducted out to 12 months. Propensity-matched results in 1,326 patients revealed that the ION Stent achieved significantly lower rates of MACE (7.5 percent vs. 12.0 percent, p=0.007) and TLF (5.5 percent vs. 8.5 percent, p=0.04) largely driven by a reduction in myocardial infarction (1.8 percent vs. 3.9 percent, p=0.02). A numerically lower but not statistically different rate of target vessel revascularization (TVR) was also observed in favor of the ION Stent (6.5 percent vs. 8.8 percent, p=0.12), supported by significantly lower late loss at nine months (0.33 plus/minus 0.52 mm vs. 0.42 plus/minus 0.56 mm, p=0.04).

"These results reinforce the relative clinical benefits of the PtCr Stent Series we have observed through physician experience in Europe and other approved markets," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "The ION Stent's advanced alloy, stent architecture and delivery system, coupled with a proven drug and polymer combination, provide interventional cardiologists with improved acute performance in treating patients with coronary artery disease."

The ION Stent System 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 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 TAXUS ATLAS program compared patients with *de novo* coronary lesions treated with the TAXUS Liberte Stent to a historical case-matched TAXUS Express® Stent control group.

In the U.S., the TAXUS Element Stent System will be commercialized as the ION<sup>™</sup> Paclitaxel-Eluting Platinum Chromium Coronary Stent System. 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.

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.

## **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: <a href="https://www.bostonscientific.com">www.bostonscientific.com</a>.

## **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 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.

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