

## **Boston Scientific Platinum Chromium ION™ Stent Demonstrates Positive Outcomes in PERSEUS Clinical Program**

NATICK, Mass. and SAN FRANCISCO, Nov. 8, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) reports positive long-term data from the PERSEUS clinical program, which demonstrated favorable two-year safety and effectiveness outcomes for the [ION™ \(TAXUS Element\) Paclitaxel-Eluting Platinum Chromium Stent System](#) versus prior-generation paclitaxel-eluting stents. Results were presented today by PERSEUS clinical program Principal Investigators Louis Cannon, M.D., of the Cardiac and Vascular Research Center of Northern Michigan in Petoskey, Michigan, and Dean Kereiakes, M.D., Medical Director at The Christ Hospital Heart and Vascular Center and The Lindner Research Center in Cincinnati, at the Cardiovascular Research Foundation's annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium in San Francisco.

"The PERSEUS trials build on the extensive TAXUS clinical program and extend the consistent outcomes seen with prior-generation paclitaxel stents to the platinum chromium ION Stent platform," said Dr. Cannon. "The excellent clinical results at two years confirm the ION Stent's safety and efficacy in workhorse lesions and suggest superior performance relative to bare-metal stents in small vessels. In addition, I have found the new alloy and stent design to offer increased flexibility, visibility and deliverability."

### **PERSEUS Workhorse and Small Vessel Trials**

Dr. Cannon presented results from the prospective, randomized pivotal PERSEUS Workhorse trial, which demonstrated comparable safety and efficacy at two years for the ION Stent compared to the Boston Scientific TAXUS® Express® Stent in more than 1,200 patients with *de novo* workhorse lesions. Both stents showed similar rates of composite measures for target lesion failure (TLF) and major adverse cardiac events (MACE). Individual safety measures of cardiac death, myocardial infarction (MI), and stent thrombosis remained low at two-year follow-up, demonstrating durable outcomes and successful transfer of the paclitaxel drug and polymer technology to the platinum chromium thin-strut platform.

Results were also presented from the PERSEUS Small Vessel trial, which compared the ION Stent in 223 patients with small vessels (greater than or equal to 2.25 to <2.75 mm diameter) to a matched historical control group of 125 patients treated with the Express® bare-metal stent. The ION Stent demonstrated similar safety and superior performance at two years compared to the Express Stent with significantly lower propensity-adjusted rates of target lesion revascularization (TLR, 7.1 percent vs. 20.8 percent, p=0.009) in patients with lesions in small vessels.

### **PERSEUS-ATLAS Trial Comparison**

In an analysis of the PERSEUS and TAXUS ATLAS clinical trial programs, Dr. Kereiakes presented results that demonstrated safety outcomes favoring the ION (TAXUS Element) Stent compared to the Boston Scientific second-generation TAXUS® Liberte® Paclitaxel-Eluting Stent. 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-matched results revealed that the ION Stent achieved significantly lower rates of MACE at two years (11.5 percent vs. 15.1 percent, p=0.04) and a numerically lower rate of TLF (8.2 percent vs. 11.0 percent, p=0.07), driven mainly by a reduction in MI (2.5 percent vs. 4.9 percent, p=0.02).

"The significantly lower rates of MACE and MI in this propensity-matched analysis demonstrate that the platinum chromium alloy, new stent design and thinner struts of the ION Stent may favorably influence clinical outcomes," said Dr. Kereiakes. "The PERSEUS trial results build confidence in this next-generation platinum chromium alloy, which, in my experience, offers noticeable performance improvements including enhanced flexibility, visibility and radial strength."

The ION Stent System features an innovative platinum chromium alloy and improved stent design to offer greater radial 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 stent delivery across challenging lesions.

The ION Stent System received U.S. Food and Drug Administration approval in April 2011.

### **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](http://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, including PERSEUS and ATLAS, and product performance, including with respect to our platinum chromium stent products. 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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