

Boston Scientific

Boston Scientific Announces FDA Approval and U.S. Launch of ION™ Platinum Chromium Stent System

NATICK, Mass., April 25, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) approval and launch of the [ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System](#), the Company's third-generation drug-eluting stent technology. The ION Stent System incorporates a unique platinum chromium (PtCr) alloy designed specifically for coronary stenting and intended to improve the acute performance of coronary stent implantation in the treatment of coronary artery disease.

(Photo: <http://photos.prnewswire.com/prnh/20110425/NE88425>)

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.

"I look forward to using the ION Stent in my daily practice, and I believe our patients will benefit from its improved acute performance," said Louis Cannon, M.D., FACC, FACA, Heart and Vascular Institute Program Director at Northern Michigan Regional Hospital in Petoskey, MI. "The platinum chromium alloy represents a leap forward in materials technology and will address many of the limitations found in older stent alloys. Exceptional stent deliverability offers cardiologists the potential to treat patients with difficult-to-reach lesions."

"The Company has made significant investments in the platinum chromium alloy, and our success with the PtCr Stent Series in Europe and other international markets has confirmed that stent material really matters," said Hank Kucheman, Executive Vice President and Group President, Cardiology, Rhythm and Vascular for Boston Scientific. "We believe the PtCr platform sets a new standard for drug-eluting stent performance and represents the future of coronary stenting."

The ION Stent offers physicians and their patients the broadest size matrix on the market, and includes both monorail® and over-the-wire versions, with sizes ranging in diameter from 2.25 mm to 4.00 mm and lengths of 8 mm to 38 mm.

Outside the U.S., including CE Mark countries where it was approved in May 2010, the ION Stent System is commercialized as the TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System. The ION Stent is backed by the proven safety and efficacy of the TAXUS clinical program, which spans 10 years of research in nearly 50,000 patients in 28 pre- and post-market studies.

The ION Stent has been evaluated in the PERSEUS trial, which reported 12-month results in March 2010, demonstrating positive safety and efficacy outcomes in workhorse lesions compared to the TAXUS® Express2® Stent System. The PERSEUS clinical program compared the ION Stent to prior-generation Boston Scientific stents in more than 1,600 patients in two parallel trials at 90 centers worldwide. In April 2011, results from an analysis of pooled patient-level data from 2,298 patients enrolled in the PERSEUS and TAXUS ATLAS clinical trials showed that the ION Stent demonstrated significantly lower rates of major adverse cardiac events, target lesion failure and myocardial infarction compared to the TAXUS® Liberte® Paclitaxel-Eluting Stent System.

"The positive clinical data from our PtCr Series trials support the acute performance benefits provided by our new platinum chromium stent platform," said Keith D. Dawkins, M.D., Senior Vice President and Chief Medical Officer for Boston Scientific's Cardiology, Rhythm and Vascular Group. "The PERSEUS data confirmed that the proven TAXUS drug and polymer combination has been successfully transferred to the advanced ION Stent platform with excellent performance and comparable safety and efficacy."

In October 2009, the Company received CE Mark approval for the PROMUS Element™ Everolimus-Eluting Stent System. The Company anticipates FDA approval for the PROMUS Element Stent System in mid 2012. The product incorporates the same platinum chromium alloy, innovative stent design and advanced catheter delivery system of the ION Stent System. In the U.S., the PROMUS Element 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: 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, our market share of that 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.

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