

Boston Scientific Announces European Approval and Launch of OMEGA™ Platinum Chromium Stent System

Third-generation bare-metal stent offers improved acute performance in treating patients with coronary artery disease

NATICK, Mass., March 7, 2011 [/PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced it has received CE Mark for its OMEGA™ Platinum Chromium Bare-Metal Coronary Stent System, the Company's third-generation coronary stenting technology. It incorporates Boston Scientific's unique platinum chromium (PtCr) alloy designed specifically for coronary stenting and is intended to provide interventional cardiologists with a bare-metal stent with improved acute performance in treating patients with coronary artery disease. The Company will immediately begin marketing the OMEGA Stent System in the European Union and other CE Mark countries.

"In my experience, the platinum chromium alloy and design used in the OMEGA Stent offer excellent deliverability, visibility and conformability while improving radial strength and reducing stent recoil," said Antonio Colombo, M.D., Director of the Cardiac Catheterization Laboratory at Columbus Hospital and San Raffaele Hospital in Milan, Italy. "The OMEGA Stent and platinum chromium alloy offer meaningful performance improvements without the tradeoffs associated with older stent alloys."

The OMEGA Stent System is part of Boston Scientific's PtCr Stent series, which includes the TAXUS® Element™ Paclitaxel-Eluting Stent System and PROMUS Element™ Everolimus-Eluting Stent System. All three stents feature the novel PtCr alloy and an innovative stent design, which combine to offer greater radial strength and flexibility while reducing stent recoil. The higher density alloy provides superior visibility while permitting thinner struts compared to prior-generation stents(1). The enhanced delivery system features a dual-layer balloon and is engineered to improve access to challenging lesions.

"The platinum chromium PROMUS Element and TAXUS Element Stents have been well received by physicians since their launch in CE Mark countries, and we are pleased to offer a bare-metal coronary stent built on the same PtCr platform," said Mike Phalen, Executive Vice President and President, International for Boston Scientific. "The OMEGA Stent is the latest example of our commitment to continued innovation in coronary stenting. We are confident our platinum chromium technology will strengthen our worldwide stent market leadership."

"The positive clinical data from our PtCr (Element) 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 OMEGA Stent complements the PtCr Stent series, and gives interventional cardiologists the option to treat patients with a paclitaxel, everolimus or bare-metal stent."

The OMEGA Stent is offered in 48 sizes, ranging in diameter from 2.25 mm to 4.50 mm and lengths of 8 mm to 32 mm. Boston Scientific has the industry's most comprehensive coronary stent portfolio, offering physicians and their patients the broadest size matrix and the only two-drug platform. The Company received CE Mark approval for the PROMUS Element Stent System in October 2009 and for the TAXUS Element Stent System in May 2010.

The TAXUS Element Stent System will be commercialized in the U.S. as the ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System and the PROMUS Element Stent System will be commercialized as the PROMUS Element Plus Everolimus-Eluting Platinum Chromium Coronary Stent System. Both systems incorporate the same platinum chromium alloy, innovative stent design and advanced catheter delivery system.

The Company anticipates U.S. Food and Drug Administration approval for the ION Stent System in mid 2011, and mid 2012 approval for the PROMUS Element Plus Stent System. CE Mark approval for the PROMUS Element Plus Stent System is expected in the second half of 2011. In Japan, the Company expects approval for the TAXUS Element Stent System in late 2011 or early 2012, and mid 2012 for the PROMUS Element Stent System.

In the U.S., the OMEGA Stent System, ION Stent System and PROMUS Element Plus Stent System are investigational devices, 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 clinical trials, regulatory approvals, competitive offerings, product performance and our market position. 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.

(1) Based on bench testing. Data on file with Boston Scientific.

CONTACT: Erik Kopp

508-650-8660 (office)

erik.kopp@bsci.com

Media Relations

Boston Scientific

Corporation

Sean Wirtjes

508-652-5305 (office)

investor_relations@bsci.com

Investor Relations

Boston Scientific

Corporation

SOURCE Boston Scientific Corporation

<https://news.bostonscientific.com/news-releases?item=59309>