

Boston Scientific Begins Clinical Trial Enrollment for OMEGA™ Platinum Chromium Stent System

NATICK, Mass., Oct. 5, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) has started patient enrollment in the OMEGA clinical trial, designed to evaluate the safety and effectiveness of the Company's OMEGA™ Platinum Chromium Bare-Metal Coronary Stent System in treating patients with a single coronary artery lesion. This prospective, single-arm trial will enroll 328 patients at 40 sites in the U.S. and Europe. The first patient was enrolled this week by Prof. Andrejs Erglis, M.D., OMEGA Principal Investigator, at Paul Stradins Clinical University Hospital in Riga, Latvia. The trial's Coordinating Principal Investigators are John Wang, M.D., of Union Memorial Hospital in Baltimore, Maryland, and Prof. Christian Hamm, M.D., of the Kerckhoff Heart and Thorax Center in Bad Nauheim, Germany.

"I am enthusiastic about enrolling patients in the OMEGA trial and the potential this advanced bare-metal stent platform holds as a treatment option for patients with coronary artery disease," said Dr. Wang. "The new alloy and design of the OMEGA stent promise to offer improved deliverability and visibility, even in patients with complex and challenging anatomy."

The primary endpoint of the OMEGA trial is nine-month target lesion failure (TLF), a composite measure that includes target lesion revascularization, myocardial infarction and cardiac death. TLF rates will be compared to a pre-specified performance goal based on historical clinical studies of cobalt-chromium and stainless steel bare-metal stents. Patients will undergo clinical follow-up at 30 days, nine months and 12 months post-procedure. Trial data will be used to support U.S. Food and Drug Administration (FDA) approval.

The OMEGA Stent System is part of Boston Scientific's Platinum Chromium (PtCr) Stent series, which includes the [ION™ Paclitaxel-Eluting Stent System](#)(1) and the PROMUS Element™ Everolimus-Eluting Stent System(2). This family of stents features 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 enhanced visibility while permitting thinner struts compared to prior-generation Boston Scientific stents(3).

"Our platinum chromium drug-eluting stents have been well received by physicians in approved markets, and we look forward to offering a bare-metal stent in the U.S. built on the same advanced 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 will complement our existing portfolio and give interventional cardiologists the option to treat patients with paclitaxel-eluting, everolimus-eluting or bare-metal stents."

The OMEGA Stent received CE Mark approval in March 2011. It is offered in 48 sizes, ranging in diameter from 2.25 mm to 4.50 mm and lengths from 8 mm to 32 mm. 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 ION Stent System received FDA approval in April 2011. Boston Scientific has the industry's most comprehensive coronary stent portfolio, offering physicians and their patients the broadest size matrix and two distinct drug-polymer platforms.

In the U.S. and at participating E.U. clinical sites, the OMEGA Stent System is an investigational device, limited by applicable law to investigational use and not available for sale.

(1) Sold in CE Mark countries as the TAXUS® Element™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System.

(2) In the U.S., the PROMUS Element™ Stent System is an investigational device, limited by applicable law to investigational use and not available for sale.

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

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 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.

CONTACT:

Erik Kopp
508-650-8660 (office)
Media Relations
Boston Scientific Corporation
erik.kopp@bsci.com

Sean Wirtjes
508-652-5305 (office)
Investor Relations
Boston Scientific Corporation
investor_relations@bsci.com

SOURCE Boston Scientific Corporation

<https://stage.mediaroom.com/bostonscientific/omega-stent-system-clinical-trial-enrollment>