Boston Scientific

Boston Scientific Supports New Clinical Trial to Evaluate Platinum Chromium Coronary Stents in Treating Heart Attack Patients

HORIZONS II AMI trial to enroll up to 10,000 patients worldwide, making it the largest randomized trial to study coronary stents in heart attack patients

NATICK, Mass. and CHICAGO, March 26, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces its support of the HORIZONS II AMI clinical trial, which is designed to evaluate the safety and efficacy of the PROMUS Element™ Plus Everolimus-Eluting Platinum Chromium (PtCr) Coronary Stent compared to the OMEGA™ Platinum Chromium Bare-Metal Stent in patients experiencing an acute myocardial infarction (AMI), commonly referred to as a heart attack. The trial is co-funded by Boston Scientific Corporation and The Medicines Company (NASDAQ: MDCO). The Cardiovascular Research Foundation (CRF) will act as the Academic Research Organization (ARO). An overview of the trial design was presented at the American College of Cardiology Annual Scientific Sessions by Gregg W. Stone, M.D., Professor of Medicine and Director of Research and Education at the Center for Interventional Vascular Therapy at Columbia University Medical Center/New York-Presbyterian Hospital and Global Principal Investigator of the trial.

HORIZONS II AMI is a randomized, double-blind, superiority clinical trial that plans to enroll 7,000 to 10,000 patients at up to 400 sites worldwide, making it the largest randomized trial to study coronary stents in heart attack patients. The trial will compare the PROMUS Element Stent to the OMEGA Stent in patients undergoing primary percutaneous coronary intervention (PCI) for ST segment elevation acute myocardial infarction (STEMI). All patients will be pre-treated with Bivalirudin, Aspirin and Prasugrel, and then randomized to Clopidogrel or Prasugrel at 30 days post-procedure. The two primary clinical endpoints are target lesion revascularization (TLR) and stent thrombosis at 12 months. The study is designed to have sufficient power to demonstrate superiority for both endpoints. Clinical follow-up will occur at 30 days, six months, and every 12 months out to three years. The non-inferiority pharmacology endpoint is death, MI, stroke, stent thrombosis or TIMI (thrombolysis in myocardial infarction) major/minor bleeding between one and 15 months. Patient enrollment in the trial is scheduled to begin in late 2012. Data from the trial is expected to be used to support an expanded indication for the PROMUS Element Stent for the treatment of STEMI patients.

"Heart attack patients are frequently treated with bare-metal stents, and remain at high risk for death and stent thrombosis despite successful percutaneous coronary angioplasty," said Dr. Stone. "As the largest primary PCI randomized trial ever performed in heart attack patients, HORIZONS II AMI is expected to provide essential guidance for physicians as to which stents and drugs will optimize outcomes following a heart attack."

The HORIZONS II AMI trial builds on results from the original HORIZONS AMI trial, which evaluated 3,006 patients randomized to receive either drug-eluting stents or bare-metal stents for the treatment of AMI. Data from that global trial were used to support U.S. Food and Drug Administration approval for an expanded indication to treat AMI patients with the ION™ Paclitaxel-Eluting Platinum Chromium Coronary Stent System and the TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System, which was received in February 2012. These devices are currently the only drug-eluting stent systems in the U.S. with an approved indication to treat patients with AMI.

"Boston Scientific continues to support large clinical trials that provide the medical community with data that can be used in combination with broader clinical judgment to develop optimal treatment strategies for challenging patient and lesion subsets," said Keith D. Dawkins, M.D., Global Chief Medical Officer for Boston Scientific. "We look forward to the results of this trial comparing the latest generation of drug-eluting and bare-metal stents on the advanced PtCr Element platform."

More than 100,000 PCI procedures are performed annually on patients suffering from acute myocardial infarction.

The safety and effectiveness of the PROMUS Element Plus Stent System have not been established in patients with AMI. The OMEGA Bare-Metal Stent System is an investigational device in the U.S. and is not available for sale.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that 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 regulatory approvals including new indications, clinical trials, product performance and clinical outcomes. 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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