Boston Scientific

Boston Scientific Initiates Study Of Promus PREMIER™ Coronary Stent System In Underserved Patient Populations

First Patient Enrolled in PLATINUM Diversity Trial Evaluating Performance in Women, Black Americans, Latinos/Hispanics, Native Americans and Alaska Natives with Coronary Artery Disease

MARLBOROUGH, Mass., Oct. 20, 2014 /PRNewswire/ -- As part of its commitment to innovation and improving patient outcomes, Boston Scientific Corporation (NYSE: BSX) has initiated the PLATINUM Diversity trial to evaluate the clinical performance of the Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System in underserved patient populations, including women and people of color. The Promus PREMIER Stent System is the company's latest durable polymer drug-eluting stent (DES) and is approved by the U.S. Food and Drug Administration (FDA) to treat coronary artery disease. Wayne Batchelor, M.D., F.A.C.C., F.S.C.A.I., and co-principal investigator, enrolled the first patient in the PLATINUM Diversity trial at Tallahassee Memorial Hospital, in Tallahassee, Florida.

Historically, large-scale clinical trials in cardiology have had a disproportionately low inclusion of women and non-white patients. As a result, physicians have had little data on which to base their clinical decisions when treating these patients. The PLATINUM Diversity trial is aligned with recent actions taken by the FDA, including implementation of FDASIA 907: Inclusion of Demographic Subgroups in Clinical Trials, and with the Boston Scientific Close the Gap education initiative which aims to promote health equity and ensure all patients receive optimal health care regardless of age, gender, race, ethnicity or primary language.

"Creating a treatment plan specifically tailored to underrepresented populations has long been a challenge in clinical practice due to the lack of specific outcomes data from cardiovascular clinical trials," said Roxana Mehran, M.D., director of Interventional Cardiovascular Research and Clinical Trials at Icahn School of Medicine at Mount Sinai Medical Center and principal investigator. "I am excited to be part of a trial that aims to fill the data demographic gap in the stent space and provides physicians with additional knowledge to make the best treatment decisions possible for their patients."

The PLATINUM Diversity trial is an observational, prospective, multicenter, open-label, single-arm, post-approval study that will enroll up to 1,500 patients from understudied populations, specifically women, black Americans, Latinos/Hispanics, American Indians or Alaska Natives, at up to 65 sites in the U.S. The primary study endpoint is the rate of the composite of death, myocardial infarction and target vessel revascularization through 12 months. Initial data are expected to be available in 2016.

"The number of minority and female patients participating in clinical trials is often not representative of disease epidemiology," said Dr. Batchelor. "Since different populations may respond differently to various therapies, it is important that we generate data to help clinicians make evidence-based treatment decisions for all patients."

According to the U.S. Centers for Disease Control and Prevention, cardiovascular disease is the leading cause of death for all Americans, including women and minorities.[i] Despite this reality, women represent less than one-third of those in cardiovascular trials conducted since 2006;[ii] black Americans represent about 12 percent of the U.S. population, yet they comprise just five percent of patients in clinical trials.[iii]

"We know that more women are dying from heart disease than any other cause. WomenHeart is advocating that the FDA implement strategies to ensure appropriate representation of women in clinical research and that results from trials be analyzed, reported by sex and easily accessible," said Lisa M. Tate, chief executive officer, WomenHeart: The National Coalition for Women with Heart Disease. "Doctors and patients can't assess which treatment is best if meaningful data for women are not available."

The PLATINUM Diversity trial, with its focus on the use of drug-eluting stent technology in women and minorities, further demonstrates the commitment of Boston Scientific to develop and conduct innovative clinical trials that provide important data to help physicians and patients make informed decisions.

About Coronary Artery Disease
Coronary artery disease is a narrowing of blood vessels that supply blood and oxygen to the heart. Patients with coronary artery disease may experience pain, shortness of breath and fatigue. They may also be at risk for a heart attack. One treatment option is the placement of a stent in the artery to help keep it open and allow the blood to flow more freely.

About the Promus PREMIER Stent System
The Promus PREMIER Stent System was developed with extensive input from interventional cardiologists and is designed to provide best in class acute and clinical outcomes.

The everolimus drug and polymer stent coating have been studied in multiple randomized clinical trials demonstrating long-term safety and efficacy. The PLATINUM Clinical Trial Program demonstrated exceptional safety and efficacy of the PROMUS Element™ Stent System (Platinum Chromium Everolimus-Eluting stent) when compared to the Xience V™ Stent (Cobalt Chromium Everolimus-Eluting stent). Further review of the PLATINUM data demonstrated that the PROMUS Element Stent System is associated with significantly less vessel straightening in severely angulated lesions and has resulted in numerically lower clinical event rates out to three years.

The Promus PREMIER Stent System received CE Mark approval in February 2013 and has been available in the U.S. since November 2013.

About Close the Gap
Close the Gap is a solution-oriented health equity initiative. In partnership with health care providers, professional societies, industry and patient advocacy groups, Close the Gap works to eliminate health care disparities by educating patients and advocating for adherence to clinical guidelines.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

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.

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[i] http://www.cdc.gov/nchs/data/nvsr/nvsr62/nvsr62_06.pdf; Accessed 9/30/14
[ii] Eur Heart J (2011) 32 (11): 1362-1368. doi: 10.1093/eurheartj/ehr048
[iii] http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM334959.pdf

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