Boston Scientific

Primary Endpoint from Study of Drug Eluting Coronary Stent in Underserved Patient Populations Presented at TCT 2016

The PLATINUM Diversity Study Provides Much Needed Data about Women and Minority Patients, Who are Under-represented in Cardiology Clinical Trials

WASHINGTON and MARLBOROUGH, Mass., Nov. 1, 2016 /PRNewswire/ -- As part of the commitment to support health equity for all patients, Boston Scientific Corporation (NYSE: BSX) sponsored the PLATINUM Diversity study to evaluate the clinical outcomes of the Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System in women and minorities. The clinical endpoints were presented today at the 28th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

In this study, there were no significant outcome differences between white men and women or minorities for the composite primary endpoint of death, myocardial infarction (MI) or target vessel revascularization (TVR) at 12 months. The composite death/MI/TVR rate was 7.6 percent for white men compared to 8.6 percent for women (p=0.33), and 9.6 percent for minorities (p=0.08). Additionally, secondary endpoint results were as follows (differences with p<0.05 were statistically significant):

- All-cause death: 2.2 percent for white men compared to 3.4 percent for women (p=0.04), and 3.7 percent for minorities (p=0.03).
- MI: 1.1 percent for white men compared to 1.9 percent for women (p=0.06), and 3.1 percent for minorities (p=0.0002).
- TVR: 5.5 percent for white men compared to 4.6 percent for women (p=0.27), and 5.4 percent for minorities (p=0.97)
- Definite or probable stent thrombosis: 0.7 percent for white men compared to 0.9 percent for women (p=0.55), and 1.2 percent for minorities (p=0.22).

"Most clinical trials examine how any given treatment impacts patient outcomes; however, given that much of an individual's health is determined by non-clinical factors, we thought it important to design the PLATINUM Diversity study in order to better understand the nature and magnitude of outcome disparities that exist for under-represented groups after contemporary coronary stent procedures," said Wayne Batchelor, M.D., co-principal investigator and chair of the Interventional Cardiology Council at Tallahassee Memorial Hospital, Tallahassee, Florida.

"The initial evaluation of the primary endpoint is the first of many analyses that we believe will provide invaluable insights into the social, behavioral and economic determinants of health in women and minorities who undergo coronary stent procedures," said Roxana Mehran, M.D., co-principal investigator and director of the Office of Interventional Cardiovascular Research and Clinical Trials of Mount Sinai Heart and professor of Cardiology and Population Health Science and Policy at Icahn School of Medicine at Mount Sinai in New York City.

Heart disease takes a greater toll on certain racial and ethnic groups yet historically, large-scale clinical trials in cardiology have had a disproportionately low inclusion of women and minorities. As a result, physicians have had little data on which to base their clinical decisions when treating these patients. The PLATINUM Diversity study was initiated in October 2014 to provide important insights that can ultimately help physicians customize treatment plans for patient-specific demographics and socioeconomic status.

"The PLATINUM Diversity study is tangible evidence of the commitment by Boston Scientific to raise awareness of the needs of underserved patient communities across the country, and is a critical first step in advancing care for all patients," says Paul Underwood, M.D., medical director of clinical interventional cardiology at Boston Scientific. "Our hope is that these 'real-world' results from the PLATINUM Diversity study will help clinicians, researchers and advocates understand the existing challenges so that we can work collaboratively to close the gender, race and ethnicity gap when treating cardiovascular disease."

The PLATINUM Diversity study is an observational, prospective, multicenter, open-label, single-arm, post-approval study that enrolled 1,501 patients at 52 sites in the U.S. from understudied populations, specifically women, African Americans, Latinos/Hispanics, American Indians or Alaska Natives. All patients in this single arm study received at least one Promus PREMIER drug-eluting stent. Patient data from the PROMUS Element™ Plus Stent System post-approval study will be included in the full analysis to allow for comparisons to white men, increasing the total number of patients to 4,188. The Promus PREMIER stent system received CE Mark approval in February 2013 and has been available in the U.S. sinceNovember 2013. The PROMUS Element Plus stent system received CE Mark approval in 2009 and FDA approval in 2011.

About Coronary Artery Disease
Coronary artery disease (CAD) – the most common type of heart disease – is a narrowing of blood vessels that supply blood and oxygen to the heart. An estimated 15 million Americans have CAD.[1] These patients may experience pain, shortness of

breath, fatigue and may 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 to the heart.

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.[2] Despite this reality, women represent less than one-third of those enrolled in cardiovascular trials conducted since 2006.[3] Black Americans represent about 12 percent of the U.S. population, have the highest heart disease death rate, and yet they comprise just five percent of patients in cardiovascular clinical trials.[4,5] Hispanics, now the largest racial/ethnic group in America, representing nearly 16 percent of the U.S. population, have the highest risk factor profile, but account for a mere one percent of study patients.[6,7]

About Boston Scientific
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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 our business plans, regulatory approvals and product performance and impact. 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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