Boston Scientific

New Data from PLATINUM Diversity Study Presented at SCAI 2017 Provide Important Insights Beyond Traditional Clinically-Reported Endpoints

Analyses Evaluated the Impact of Ethnicity, Gender and Income on Cardiovascular Outcomes

NEW ORLEANS and MARLBOROUGH, Mass., May 12, 2017 /PRNewswire/ -- New analyses from the Boston Scientific Corporation (NYSE: BSX) sponsored PLATINUM Diversity study underscore the need for greater understanding of the clinical and nonclinical barriers that can adversely affect stent-related outcomes. Aligned with the Boston Scientific "Close the Gap" health equity initiative, PLATINUM Diversity is a first-of-its-kind study focusing exclusively on women and minorities with coronary artery disease that is designed to shed light into the clinical, social, behavioral and economic determinants of health treatment outcome disparities in these groups. The findings of these new analyses were presented today during the Late-Breaking Clinical Trial Session at the 40th Annual Society for Cardiac Angiography and Interventions (SCAI) Scientific Sessions in New Orleans.

"Clinicians need data that explore both the clinical and social determinants of health that influence outcomes in cardiovascular disease in order to provide all patients with the best possible care," said Wayne Batchelor, M.D., co-principal investigator and chair of the Interventional Cardiology Council at Tallahassee Memorial Hospital, Tallahassee, Florida. "These data from PLATINUM Diversity provide important insights for the cardiology community to consider in addressing inequities in cardiovascular care."

Historically, large-scale clinical trials in cardiology have had a disproportionately low inclusion rate of women and non-white patients, and disparities in clinical trial enrollment are a reflection of differences in treatment rates seen in clinical practice.[1] New analyses of PLATINUM Diversity data show the impact of demographic and economic factors on outcomes one year after stent implantation:

- Several clinical and angiographic risk factors, including diabetes, renal disease, hypertension and coronary calcification were more prevalent in non-whites and women compared to white men, whereas white men more likely presented with visible thrombus;
- Unadjusted rates of combined death, myocardial infarction (MI) and target vessel revascularization (TVR) were higher in minority women than white men;
- Unadjusted rates of death were higher in white women and minority men than white men;
- Unadjusted rates of combined death and MI were higher in minority men and women than white men;
- After accounting for the differences in baseline clinical and angiographic risk factors, minority women still showed a higher rate of combined death, MI and TVR, combined death and MI and MI alone than white men, a result driven by a nearly four-fold increased risk of MI;
- After accounting for the differences in baseline clinical and angiographic risk factors, rates of repeat hospitalization for TVR and stent thrombosis (ST) were similar across all four groups included in the analysis (white men, white women, non-white men and non-white women).

"The most vulnerable populations who are at the greatest risk of heart disease are the ones who are being studied in clinical trials the least," said Paul Underwood, M.D., medical director of clinical interventional cardiology at Boston Scientific. "It's of critical importance to us to have real-world clinical evidence of how our products work in all populations, including those most susceptible to coronary artery disease. We hope that the insights yielded from PLATINUM Diversity are a catalyst for industry-wide change, beginning in clinical trial recruitment."

The analyses of PLATINUM Diversity also revealed socioeconomic disparities. Among patients who disclosed annual household income, the study indicated significant differences in the primary clinical endpoint of the composite of death, MI and TVR at 12 months.

Annual household income	Composite rate of death, MI and TVR at 12 months
<$25,000	9.8%
$25,000-$49,999	8.1%
>$50,000	4.1%

After adjustment for all other clinical and angiographic variables, annual income remained an independent predictor of death

and combined death and MI.

"These are daunting results for our patients with low socio-economic status, and a call to action to pay close attention to their post hospital care and follow up," said Roxana Mehran, M.D., FACC, co-principal investigator, professor of medicine (cardiology) and population health science and policy director of interventional cardiovascular research and clinical trials at the Icahn School of Medicine at Mount Sinai.

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™ Everolimus-Eluting Platinum Chromium Coronary Stent System. Patient data from the PROMUS Element™ Plus post-approval study were included in the full analysis to allow for comparisons to white men, increasing the total number of patients to 4,188.* The study's primary endpoints were presented at the 28th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, on November 1, 2016.

The Promus PREMIER Stent System received CE Mark approval inFebruary 2013 and has been available in the U.S. since November 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.[2] These patients may experience pain, shortness of breath and 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.[3] Despite this reality, women represent less than one-third of those enrolled in cardiovascular trials conducted since 2006.[4] 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.[5,6] 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.[7,8]

About Close the Gap
PLATINUM Diversity is part of the Boston Scientific Close the Gap initiative, which aims to promote health equity by reducing barriers to care for all patients. In partnership with health care providers, the clinical community, 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. To learn more, visit www.your-heart-health.com.

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 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.

**While patients in the PLATINUM Diversity study received the Promus PREMIER Stent, data were pooled and compared with data from white male patients who received the PROMUS Element Plus Stent, an earlier generation stent with similar properties and outcomes relevant for demographic comparisons.*

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