Boston Scientific Promus PREMIER™ And SYNERGY™ Drug-Eluting Stent Systems Provide Exceptional Safety And Efficacy Data

Boston Scientific Corporation (NYSE: BSX) reports positive results from two trials evaluating new, innovative drug-eluting stent (DES) technologies, which are emerging treatment options for coronary heart disease. Data from the first human use NG PROMUS Clinical Trial evaluating the safety and effectiveness of the Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System, and two-year follow-up data from the EVOLVE Trial comparing the safety and effectiveness of the SYNERGY™ Everolimus-Eluting Bioabsorbable Polymer-Coated Platinum Chromium Coronary Stent System to the PROMUS Element™ Stent System were presented today at the annual EuroPCR Scientific Program in Paris.

The NG PROMUS Clinical Trial evaluated the clinical and angiographic outcomes for the Promus PREMIER Stent System at 30 days. John Ormiston, M.D., of Mercy Angiography, Auckland City, New Zealand is the primary investigator for the trial and presented data at the conference.

"The Promus PREMIER Stent demonstrated excellent safety and effectiveness with zero percent target lesion revascularization and stent thrombosis," said Dr. Ormiston. "In addition, the rate of technical success, the primary endpoint of the trial, was very high at 99.2 percent. The Promus PREMIER Stent System truly is a major step forward in stent technology."

The Promus PREMIER Stent System features the only customized stent architecture of its kind providing strength without compromising flexibility. An enhanced low-profile delivery system with a shorter, more visible tip, dual-layer balloon and Bi-Segment™ inner lumen catheter is designed to facilitate precise stent delivery across challenging lesions.

Two-year follow-up data from the EVOLVE Trial were also presented today at EuroPCR by Professor Ian Meredith, director of MonashHeart, at Monash Medical Centre in Melbourne, Australia. The primary clinical and angiographic endpoints of this non-inferiority study, which compares the SYNERGY™ Stent to the PROMUS Element Stent, have already been published.

"The clinical results of the SYNERGY™ Stent in EVOLVE continue to impress with respect to safety and efficacy. At two years, we see no increase in the 1.1 percent target lesion revascularization (TLR) and zero percent stent thrombosis rates that we observed in the full-dose SYNERGY™ Stent at one year," said Professor Meredith. "Interestingly, the difference in TLR between the PROMUS Element Stent at 6.1 percent and the SYNERGY™ Stent at 1.1 percent is approaching statistical significance (p=0.07). This is encouraging, as it supports our hypothesis that the bioabsorbable polymer coating could provide a long term benefit over durable polymer coated DES."

The SYNERGY™ Stent features a bioabsorbable PLGA polymer and everolimus drug combination to create a low initial weight, ultra-thin, uniform coating that is applied to the abluminal (outer) surface of the stent. The proprietary PLGA polymer completes absorption shortly after drug elution ends at three months, leaving only a bare platinum chromium stent. This technology provides the same level of restenosis reduction as a conventional everolimus-eluting stent while potentially offering faster and more complete vessel healing after stent implantation, which could reduce the required duration of post-procedure dual antiplatelet therapy.

"The Promus PREMIER and SYNERGY™ Stent Systems are the latest additions to our growing pipeline of drug-eluting stent technologies," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "These innovations reflect our commitment to interventional cardiologists and the patients they serve."

Coronary heart disease is a narrowing of the vessels that supply blood and oxygen to the heart. Recent statistics from the European Heart Network and the European Society of Cardiology show it is the single most common cause of death in Europe accounting for 1.8 million deaths in Europe per year. Patients living with coronary heart disease, also known as 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.

The Promus PREMIER and SYNERGY™ Stents have CE Mark approval. In the United States and Japan, they are investigational devices and are limited by applicable law to investigational use only and are not available for sale.

About the NG PROMUS Clinical Trial
The NG PROMUS Clinical Trial supports the safety and efficacy of the Promus PREMIER Stent System.

About the EVOLVE Trial
EVOLVE is the first human use prospective, randomized, single-blind, study evaluating the non-inferiority of the SYNERGY™ Stent, which employs a bioabsorbable polymer coating applied to the abluminal (outer) surface of the stent, compared to the Boston Scientific PROMUS Element Stent, which utilizes a durable polymer coating applied to the entire stent (inner and outer) surface.

To view the Multimedia News Release including backgrounders and images, please click here: https://www.epresspack.net/boston-scientific-at-europcr-2013/news/stent

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, 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.

---

https://news.bostonscientific.eu/2013-05-22-Boston-Scientific-Promus-PREMIER-TM-And-SYNERGY-TM-Drug-Eluting-Stent-Systems-Provide-Exceptional-Safety-And-Efficacy-Data