Boston Scientific

One-Year EVOLVE Trial Clinical Results Confirm Comparable Safety And Effectiveness Data Of The Boston Scientific SYNERGY™ Stent Versus PROMUS Element™ Platinum Chromium Stent

NATICK, Mass., May 15, 2012 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces that theSYNERGY™ Everolimus-Eluting Bioabsorbable Polymer-Coated Platinum Chromium Coronary Stent System demonstrated non-inferior results in treating *de novo* coronary artery lesions at one year compared to thePROMUS Element™ Everolimus-Eluting Platinum Chromium Stent System in the EVOLVE First Human Use Trial. The trial reported one-year clinical and six-month intravascular ultrasound (IVUS) outcomes data, evaluating the safety and effectiveness of the bioabsorbable abluminal polymer-coated SYNERGY Stent. Results were presented today at the annual EuroPCR Scientific Program in Paris by Stefan Verheye, M.D., Ph.D., F.E.S.C., senior interventional cardiologist at the Antwerp Cardiovascular Institute, ZNA Middelheim Hospital, Belgium.

The EVOLVE trial previously reported the primary angiographic and clinical endpoints of non-inferiority of the SYNERGY Stent compared with PROMUS Element for late loss at 6 months and target lesion failure (TLF) at 30 days. The EVOLVE one-year trial data demonstrated that both versions of the SYNERGY Stent (loaded with both full- and half-dose everolimus) are clinically non-inferior to the PROMUS Element Stent. There were no significant differences between groups for all IVUS parameters evaluated at 6 months, including neointimal area, stent or lumen area, net volume obstruction, incomplete stent apposition or minimum lumen diameter.

"The 6-month IVUS data suggest that anti-restenotic activity is maintained with the SYNERGY stent, even after four months, when the drug and polymer coating are designed to be absorbed. Importantly, the SYNERGY Stent has shown equivalent clinical safety and effectiveness in the EVOLVE data compared to the PROMUS Element Stent. We continue to observe very low rates of revascularization and no cardiac-related deaths or stent thrombosis with SYNERGY at one year," said Dr. Verheye. "The EVOLVE data demonstrate the effectiveness of drug elution from an ultra-thin, abluminal bioabsorbable polymer with this innovative coronary stent platform."

At one year, TLF in both study arms was not statistically different from the PROMUS Element Stent (4.4 percent, 4.2 percent and 5.1 percent for the full-dose SYNERGY Stent, half-dose SYNERGY Stent and PROMUS Element Stent, respectively; p=1.00 for superiority comparison of each SYNERGY Stent version with the PROMUS Element Stent). TLF is defined as target-vessel-related cardiac death, target-vessel-related myocardial infarction (MI), or ischemia-driven target lesion revascularization (TLR). Clinical follow-up at one year demonstrated no cardiac related deaths, Q-wave MI, or stent thrombosis for any of the stent groups. Periprocedural non-Q-wave MIs had previously been observed in one patient in the full-dose SYNERGY arm and three patients in the half-dose SYNERGY arm; an additional two non-Q-wave MIs occurred between 6 and 12 months in the full-dose SYNERGY arm; however, these were not considered related to the stent. Non-Q-wave MI rates were not significantly different between groups at any time point up to and including one year (3.3 percent for full-dose SYNERGY [p=0.11], 3.2 percent for half-dose SYNERGY [p=0.12], each compared to 0.0 percent for PROMUS Element). TLR was 1.1 percent for both SYNERGY doses versus 5.1 percent for PROMUS Element (p=0.21). Additionally, target vessel revascularization (TVR) was noted to be numerically lower with the SYNERGY Stent, but the difference was not statistically significant (3.3 percent for full-dose SYNERGY [p=0.09] and 4.2 percent for half-dose SYNERGY [p=0.17] each compared to 9.2 percent for PROMUS Element).

"The SYNERGY Stent is a next-generation everolimus-eluting stent that combines the same platinum chromium alloy and similar design used in the PROMUS Element Stent with a novel coating created to significantly reduce the amount of polymer and drug to which the blood vessel wall is exposed, without compromising inhibition of neointimal growth," said Keith D. Dawkins, M.D., global chief medical officer for Boston Scientific. "SYNERGY is designed to address potential limitations with durable polymer coatings used on currently available drug-eluting stents, including issues with dual antiplatelet therapy interruption and duration. We continue to be pleased with the impressive clinical and angiographic results from the EVOLVE trial for this advanced coronary stent technology."

EVOLVE trial data are expected to support CE Mark approval for the SYNERGY Stent, which is expected as early as later this year, while additional larger studies are anticipated to further assess clinical event rates and the potential for reduced dual antiplatelet therapy with this novel stent technology.

The SYNERGY Stent is an investigational device, limited by applicable law to investigational use only and not available for sale.

About the SYNERGY Stent

The SYNERGY Stent uses a bioabsorbable PLGA polymer and everolimus drug combination to create an ultra-thin, uniform coating applied to the outer (abluminal) surface of the stent. After the drug has been delivered, the bioabsorbable coating is designed to absorb within four months of implantation, leaving only a bare-metal PtCr stent. This technology is designed to provide the same degree of restenosis reduction as a conventional drug-eluting stent while offering faster and more complete

vessel healing after stent implantation, which could potentially reduce the duration or allow safer interruption of post-procedure dual antiplatelet therapy. The SYNERGY Stent features the same proprietary platinum chromium alloy and similar stent design used in the PROMUS Element Stent to enable thinner struts, increased conformability, deliverability and flexibility while maintaining low recoil and excellent visibility.

About the EVOLVE First Human Use Study

EVOLVE is a prospective, randomized, single-blind, study evaluating the non-inferiority of the SYNERGY Stent, which employs an ultra-thin bioabsorbable polymer applied to the outer (abluminal) surface of the stent, compared to the PROMUS Element Stent, which utilizes a permanent durable polymer applied to the entire stent (conformal) surface. The study randomized 291 patients to one of three arms: the full-dose SYNERGY Stent (with the PROMUS Element dose of everolimus), half-dose SYNERGY Stent (half the everolimus dose of PROMUS Element), or the commercially available PROMUS Element Stent. All three stents employ a similar drug release profile.

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.

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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 and clinical trial plans, SYNERGY and PROMUS Element stent systems performance and effects. 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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