

Boston Scientific Receives CE Mark Approval for the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System, Featuring A Novel Bioabsorbable Polymer Coating

NATICK, Mass., Oct. 31, 2012 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) received CE Mark approval for the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System featuring an ultra-thin abluminal (outer) bioabsorbable polymer coating. The SYNERGY Stent is the latest innovation in drug-eluting stent technology from Boston Scientific. It is unique in that its proprietary PLGA polymer and everolimus drug coating dissipate by three months. This innovation has the potential to improve post-implant vessel healing and will eliminate long-term polymer exposure, a possible cause of late adverse events.

"With the SYNERGY Stent, drug release and polymer absorption occur in parallel and are complete at about three months after stent implantation," said Ian Meredith, M.B.B.S., Ph.D., Professor and Director of Monish Heart, at Monish Medical Centre in Melbourne, Australia and the principal investigator of the EVOLVE clinical study. "This exciting advance may improve long-term safety and efficacy compared to current durable polymer DES and perhaps even reduce the need for prolonged dual antiplatelet therapy."

The timely absorption of the SYNERGY Stent coating is the result of seven years of research and development to create what Boston Scientific believes to be the ideal blend of drug and polymer with advanced coating technologies.

"In addition to its innovative coating, the foundation of the SYNERGY Stent is our proprietary platinum chromium alloy and an enhanced stent design which allow for thinner struts, increased visibility and an extremely low crossing profile for easier deliverability," said Kevin Ballinger, president of the Interventional Cardiology division at Boston Scientific. "We believe that the result is a premium workhorse drug-eluting stent that eliminates long-term polymer exposure, promotes optimal healing and provides confident deliverability."

The SYNERGY Stent is supported by a rigorous clinical program builds on the EVOLVE six-month study results which demonstrated non-inferiority to the Boston Scientific PROMUS Element™ Stent for the primary angiographic endpoint of in-stent late loss, a proxy for efficacy. At 12 months, the SYNERGY Stent demonstrated a target lesion revascularization (TLR) rate of 1.1 percent and a stent thrombosis (ST) rate of 0.0 percent. A pivotal trial, EVOLVE II, has been designed to support U.S. Food and Drug Administration and Japanese Ministry of Health, Labor and Welfare approval of the SYNERGY Stent System and is expected to begin enrollment later this year. EVOLVE II is a global, multicenter, randomized, controlled (RCT), pivotal trial that will enroll 1,684 patients in 160 sites across the globe. Boston Scientific anticipates additional studies to assess outcomes, including the potential for reduced dual antiplatelet therapy.

The SYNERGY Stent will be available in a full range of sizes to select centers in Europe and other geographies by early 2013. This limited market release is expected to provide additional data to support the clinical and economic benefits of this novel bioabsorbable technology. A broad commercial launch of the SYNERGY Stent is planned for early 2014.

The SYNERGY Stent System is an investigational device, not available for sale in United States and Japan.

About the SYNERGY Stent

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 offering faster and more complete vessel healing after stent implantation, which could potentially reduce the duration of post-procedure dual antiplatelet therapy. The SYNERGY Stent features the Boston Scientific platinum chromium alloy and an enhanced stent design to enable thinner struts and improved deliverability while maintaining excellent conformability, flexibility, radiopacity and low recoil.

About the EVOLVE and EVOLVE II studies

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. The study randomized 291 patients to one of three arms: the full-dose SYNERGY Stent (with the PROMUS Element Stent dose of everolimus), half-dose SYNERGY Stent (half the everolimus dose of the PROMUS Element Stent), or the commercially available PROMUS Element Stent. All three stents employ a similar drug release profile. EVOLVE II is a global, multicenter, pivotal trial consisting of a prospective, one-to-one randomized (SYNERGY stent to PROMUS Element Plus stent), controlled, single-blind, non-inferiority trial (RCT); a concurrent, non-randomized, single-arm, pharmacokinetic sub-study; and a, non-randomized, single-arm, diabetes sub-study.

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.

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, new product launches and launch cadence, regulatory approvals, clinical trials and outcomes, product performance and impact, 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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