

Boston Scientific Receives FDA Approval For SYNERGY™ Bioabsorbable Polymer Drug-Eluting Stent System

New Category of Drug-Eluting Stent Approved For U.S. Patients

MARLBOROUGH, Mass., Oct. 5, 2015 /[PRNewswire](#)/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the SYNERGY™ Bioabsorbable Polymer Drug-Eluting Stent System (BP-DES) for the treatment of coronary artery disease.

With this FDA approval, Boston Scientific will commence commercialization of the first and only BP-DES in the U.S. Notably, both the drug coating and the polymer – which modulates drug release – are fully absorbed shortly after drug elution is complete at three months.

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The SYNERGY Stent provides synchronized drug and polymer absorption. It is designed to enable more rapid and complete arterial healing, and to thereby reduce the risk of complications associated with long-term polymer exposure compared to currently-used drug-eluting stents (DES) with permanent polymers.

Existing DES devices reduce coronary restenosis, but the polymer remains on the stent after the drug is delivered. Long-term exposure to the polymer may cause inflammation, which delays healing and has been associated with complications, including neoatherosclerosis and stent thrombosis. The SYNERGY Stent is designed for faster and sustained healing by eliminating long term polymer exposure.

"Data from the EVOLVE II trial, which included the most complex patient population studied in a U.S. regulatory approval stent trial, demonstrated exceptional performance and safety of the SYNERGY Stent," said Dean Kereiakes, M.D., principal investigator of the EVOLVE II trial and medical director at The Christ Hospital Heart & Vascular Center/The Lindner Research Center, Cincinnati. "The U.S. cardiology community will have access to a bioabsorbable polymer DES which will provide excellent clinical outcomes and should optimize vessel healing."

Results previously reported from EVOLVE II, a global, multi-center, randomized, single-blind, non-inferiority pivotal trial demonstrated 0% definite stent thrombosis (ST) after 24 hours. Four-year EVOLVE trial data demonstrated a continued 0% stent thrombosis rate and a very low target lesion revascularization (TLR) rate of 1.1%.

Boston Scientific will continue to advance the robust clinical program supporting the SYNERGY Stent with the initiation of the EVOLVE Short Dual Anti-Platelet Therapy (DAPT) Study, expected during the first quarter of 2016. The company has received an Investigational Device Exemption (IDE) for this prospective study designed to assess the safety of three-month use of DAPT in patients at high risk for bleeding undergoing percutaneous coronary intervention (PCI) with the SYNERGY Stent.

"The introduction of the first bioabsorbable polymer stent in the U.S. is a tremendous milestone in the evolution of stent technology," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "The SYNERGY Stent is a next generation therapy designed to improve patient outcomes and ultimately reduce health care costs associated with the treatment of coronary artery disease."

About the SYNERGY Bioabsorbable Polymer Stent

The SYNERGY Stent is the only bioabsorbable polymer stent available to patients in the U.S. It features

ultrathin stent struts with an abluminal bioabsorbable drug/polymer coating technology that is absorbed shortly after drug elution is complete at three months, thereby eliminating long-term polymer exposure. Obtain more information on the [SYNERGY Clinical Program and Research in the U.S.](#) Information is also available [for those outside the U.S.](#)

The SYNERGY Stent received CE Mark in 2012. [View or download](#) an image of the SYNERGY Stent.

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 new product launches and launch cadence, regulatory approvals, clinical trials and impact of data, 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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