Boston Scientific

New Data From EVOLVE Clinical Program Demonstrate SYNERGY™ Bioabsorbable Polymer Stent Meets Key Performance Endpoints

EVOLVE II Trial Represents the First Successful U.S. Pivotal Trial of a Bioabsorbable Polymer Stent

MARLBOROUGH, Mass., Nov. 19, 2014 /PRNewswire/ -- In the first successful U.S. pivotal trial of a bioabsorbable polymer stent, the Boston Scientific (NYSE: BSX) SYNERGY™ Everolimus-Eluting Bioabsorbable Polymer Platinum Chromium Coronary Stent System met its primary endpoint in this non-inferiority study, which evaluated the one-year rate of target lesion failure (TLF).

Additionally, favorable rates for key secondary endpoints were observed with the SYNERGY Stent. Dean Kereiakes, M.D., F.A.C.C., F.S.C.A.I., the principal investigator for the EVOLVE II Trial, presented the study results today in a Late Breaking Clinical Trial session at the American Heart Association Scientific Session 2014 in Chicago.

Key findings for the SYNERGY Stent from the EVOLVE II Trial include the following:

- At 12 months, the TLF rate was 6.4 percent per protocol (p=0.0003 for non-inferiority) and 6.7 percent for intent-to-treat (p=0.0005 for non-inferiority).
- Stent Thrombosis (ST) was rare, with Definite or Probable ST occurring in only 0.4 percent of patients through one year. No Definite ST occurred after 24 hours.

"The one-year data from the EVOLVE II Trial, particularly the exceptionally low stent thrombosis rate, are encouraging because this is a complex patient population," said Kereiakes, who is medical director at The Christ Hospital Heart & Vascular Center/The Lindner Research Center, Cincinnati. "Having a bioabsorbable polymer stent with this type of performance is important to physicians and health care systems. In addition, there is great enthusiasm for a product that is very deliverable and user-friendly. From an operator perspective, the SYNERGY Stent makes cases easier."

The EVOLVE II Trial is a global, multi-center, randomized, single-blind, non-inferiority pivotal trial designed to evaluate the performance of the SYNERGY Stent System compared to the durable polymer PROMUS Element™ Plus Drug-Eluting Stent (DES) System. The trial enrolled 1,684 patients in 125 sites worldwide, including the U.S., Canada, Europe, Australia, New Zealand, Japan and Singapore. Patients demonstrated both clinical and angiographic complexity to a degree not observed in prior U.S. pivotal trials for DES. More than 25 percent of patients had non-ST elevation myocardial infarction (NSTEMI) and approximately 75 percent of patients had AHA/ACC class B2 or C coronary lesions. The EVOLVE II Trial is part of a rigorous clinical program designed to support U.S. Food and Drug Administration (FDA) and Japanese Ministry of Health, Labor and Welfare (MHLW) approval of the SYNERGY Stent.

"The EVOLVE II Trial adds to our growing body of knowledge about the promising SYNERGY Bioabsorbable Polymer Stent, which is designed to provide early healing and freedom from long-term polymer exposure," said Kevin Ballinger, president, Interventional Cardiology, Boston Scientific. "It also supports key findings from the EVOLVE FHU study, where data through three-years demonstrate excellent long-term outcomes."

About the SYNERGY Bioabsorbable Polymer Stent
If approved by the FDA, the SYNERGY Stent would become the first 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. The SYNERGY Stent is being investigated in multiple independent, "real-world" studies across the spectrum of cardiovascular disease complexity. For more information on the SYNERGY Clinical Program in the U.S., click here. For those outside the U.S., click here.

The SYNERGY Stent is an investigational device in the U.S. and Japan, and is not available for sale in those countries. The SYNERGY Stent has CE mark approval and is available for sale in Europe. To view or download an image of the SYNERGY Stent, click here.

About Coronary Artery Disease
Coronary artery disease is a narrowing of blood vessels that supply blood and oxygen to the heart. Patients with 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.

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.

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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 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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