Boston Scientific

Boston Scientific Announces Positive Data from the EVOLVE Short DAPT study with the SYNERGY™ Bioabsorbable Polymer Stent

Study of abbreviated antiplatelet therapy for patients at high risk for bleeding after undergoing percutaneous coronary intervention

SAN FRANCISCO and MARLBOROUGH, Mass., Sept. 26, 2019 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has announced primary endpoint results from the EVOLVE Short DAPT clinical trial, the first prospective study initiated in the U.S. to examine the safety of a shortened duration of dual antiplatelet therapy (DAPT) in patients at high risk for bleeding. Results were presented during a late-breaking clinical science session at the 31st Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, in San Francisco, and demonstrated that a three-month regimen of DAPT is non-inferior to a 12-month or longer regimen in patients with an increased risk of bleeding after being treated with the SYNERGY™ Bioabsorbable Polymer (BP) Stent.

Patients within the trial were implanted with at least one SYNERGY BP stent and considered at high risk for bleeding after meeting at least one of the criteria such as: age of 75 or older with the risk of longer term DAPT deemed greater than the benefit, a history of stroke, renal insufficiency or failure, the need for chronic anticoagulation therapy or history of major bleeding in the prior 12 months. The co-primary endpoints of the study assessed the rate of death or myocardial infarction (MI) and the rate of stent thrombosis between three and 15 months. Both primary endpoints were successfully met.

"These data prospectively demonstrate a low rate of adverse events for patients who are at high risk for bleeding and who then stop DAPT at three months," said Ajay Kirtane, M.D., director of Cardiac Catheterization Laboratories at Columbia University Irving Medical Center/New York-Presbyterian Hospital and principal investigator of the EVOLVE Short DAPT trial. "This is critically important information because previously, the required duration of DAPT following implantation of current generation drug-eluting stent platforms was unknown. These data better inform physicians as to how best to tailor the recommended duration of DAPT to the bleeding risk of the patients they treat."

The global EVOLVE Short DAPT trial enrolled 2,009 patients and of those, 1,487 patients were eligible to discontinue dual-antiplatelet therapy at three months. In patients treated with a short DAPT regimen, investigators found that the rate of death or MI between three and 15 months was non-inferior in the three-month DAPT group compared to a historical control group of patients treated with 12-month DAPT (5.6% vs. 5.7%, p-value for non-inferiority was 0.002). Additionally, the rate of stent thrombosis between three and 15 months in the patients treated with three-month DAPT was 0.3%, significantly lower than the endpoint performance goal of 1.0%.

"We are pleased the study presented today provided robust safety data on shortened DAPT following implantation of the SYNERGY BP Stent for this patient population, as the reduced length of therapy can be a clinically significant differentiator," said Ian Meredith, M.D., executive vice president and global chief medical officer, Boston Scientific. "We continue to build upon the body of evidence supporting the excellent clinical outcomes of the SYNERGY BP Stent and look forward to submitting these data to regulatory authorities to support an indication for use of this stent in patients at high risk of experiencing a bleeding event."

This month, the company received CE Mark for the SYNERGY MEGATRON™ Bioabsorbable Polymer (BP) Stent, the newest stent within the SYNERGY family of products. The SYNERGY MEGATRON BP stent is designed for use in large proximal vessels and features architecture with increased strength as well as the ability to expand to 6.0mm in diameter and accommodate tapered vessels.

Please see the SYNERGY BP Stent Directions for Use for full antiplatelet prescribing information.

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 40 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 our business plans and product performance and impact. 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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