Boston Scientific

First Patient Enrolled In Boston Scientific Randomized Study Comparing WallFlex® Biliary RX Stent To Absence Of Biliary Drainage In Patients With Pancreatic Or Periampullary Cancers

NATICK, Mass., May 15, 2013 /PRNewswire/ -- The first patient has been enrolled in a clinical investigation evaluating the use of the Boston Scientific Corporation (NYSE: BSX) WallFlex® Biliary RX Stent, a self-expanding metal stent (SEMS), as a bridge to surgery compared with the absence of drainage prior to surgery. This multi-center, prospective, randomized study is expected to enroll 294 patients at leading hospitals in Australia, Belgium, Canada, France, Hong Kong, India, Italy and Japan. The first patient was enrolled by Professor Jacques Deviere of Erasme Hospital in Brussels.

"Patients with pancreatic or periampullary cancer often have high levels of bilirubin, which adversely affect their liver, cardiovascular and renal functions," said Professor Deviere. "These patients often have impaired immune response and clotting, which in turn could negatively impact the outcome of their surgical resection. Preoperative biliary drainage could potentially reverse these factors and therefore result in an improved outcome of the surgery. Published data regarding plastic stent drainage prior to surgical resection have been unfavorable and physicians are increasingly turning to self-expanding metal stents for preoperative drainage where necessary due to their large diameter. We expect this study to provide us with important data on the safety and effectiveness of this approach compared with proceeding to surgery without biliary drainage."

SEMS have long been considered the standard of care for the palliative treatment of malignant biliary strictures. This study evaluates the benefits of using SEMS in preoperative settings, with an objective of documenting clinical safety and effectiveness as compared to the standard, direct-to-surgery approach.

"Boston Scientific is committed to advancing science through investment in robust clinical research, while delivering innovative technologies designed to improve quality of life for patients," said David Pierce, president, Endoscopy, Boston Scientific. "The results of this study may indicate that using SEMS preoperatively for biliary drainage could result in better patient outcomes and prove to be more cost effective for physicians and hospitals."

The study includes WallFlex Biliary Fully Covered and Uncovered Metal Stents. The WallFlex Biliary Fully Covered Stent has a silicone polymer Permalume® Coating designed to reduce the potential for tumor/tissue ingrowth, and an integrated retrieval loop for removing or repositioning the stent in the event of incorrect placement during the initial procedure or for removal from benign strictures up to one year after placement. The stent is constructed of braided, platinum-cored Nitinol wire (Platinol™ Wire) and features three key components: radial force to help maintain duct patency and resist migration, flexibility to aid in conforming to tortuous anatomies and full-length radiopacity to enhance stent visibility under fluoroscopy.

WallFlex Biliary Stents – Fully Covered, Partially Covered and Uncovered – are available in the United States and are only indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms. The WallFlex Biliary Stents are not indicated in the United States for use in preoperative malignant biliary strictures nor for use in benign biliary strictures. The safety and effectiveness of the stent for use in the vascular system have not been established.

The WallFlex Biliary Stents are CE Marked for use in the palliative treatment of biliary strictures produced by malignant neoplasms and for treatment of benign biliary strictures.

For more information, visit Boston Scientific Endoscopy Resources online atwww.bostonscientific.com/endo-resources.

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 30 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, clinical trials and results, product performance and importance, and competitive offerings and practices. 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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