Boston Scientific

Boston Scientific WallFlex™ Esophageal Stent Gains CE Mark For The Treatment Of Refractory Benign Esophageal Strictures

NATICK, Mass., Feb. 14, 2014 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received CE Mark in Europe for its WallFlex™ Esophageal Fully Covered Stent to treat refractory benign esophageal strictures.

Benign esophageal strictures are a narrowing of the esophagus caused by scar tissue.[i] The primary treatment is dilation of the esophagus, which may need to be repeated after a period of time if the stricture recurs.[ii]

"Fully covered esophageal stents are a valid therapeutic option in patients with benign refractory esophageal strictures," said Dr. Javier Jimenez, chief of the Endoscopy Department at Complejo Hospitalario de Navarra in Pamplona, Spain. "I use the WallFlex Esophageal Stent because its small profile and radiopacity facilitate accurate placement, the migration rate is low and stent removal is usually easy."

"The advantage of the WallFlex Esophageal Fully Covered Stent is its ease of use and now removability, which allows me to treat patients with refractory benign strictures," said Peter D. Siersema, M.D., Ph.D., professor of Gastroenterology and head of the Department of Gastroenterology and Hepatology at University Medical Center in Utrecht, The Netherlands.

The Nitinol wire braided construction allows the WallFlex Esophageal Stent to provide luminal patency in the presence of strictures or tumors. The stent is designed for gradual expansion, typically complete after 24 to 72 hours, and features a Permalume™ silicone coating that is designed to prevent tumor in-growth, seal concurrent esophageal fistulas and help reduce food impaction. An additional feature is a Teflon™ coated polyester suture that enables removal from refractory benign strictures for up to eight weeks, potentially saving patients from having to visit the hospital to undergo additional dilations to treat their stricture.[iii] The WallFlex Stent also provides physicians with clear visualization during fluoroscopy, aiding in accurate placement. The progressive step flared ends assist in anchoring the stent within the esophageal lumen.

"Building on the best of Boston Scientific's industry-leading stents, the expanded indication for the WallFlex Esophageal Fully Covered Stent demonstrates our commitment to physician needs and dedication to improving patient outcomes," said David Pierce, president, Endoscopy, Boston Scientific. "This enables physicians in the European Union to provide additional options for the treatment and management of patients suffering from benign esophageal strictures."

Both fully covered and partially covered WallFlex Esophageal Stents have previously received CE Mark and U.S. Food and Drug Administration (FDA) clearance for the palliative treatment of malignant esophageal strictures. WallFlex Esophageal Stents are not approved for removal from malignant strictures and are not approved in the U.S. for the treatment of refractory benign esophageal strictures.

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, markets for our products, 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.

[i] Esophageal Stricture, Medscape.
[ii] Esophaeal Stricture - Benign, Scripps.
[iii] The WallFlex Esophageal Stent is not approved for removal from malignant strictures

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