Boston Scientific

Boston Scientific Announces FDA Clearance and U.S. and European Availability of WallFlex® Biliary RX Covered Stents

Three models of stenting system now available for palliative treatment of malignant common bile duct strictures

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NATICK, Mass., Oct. 6 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its WallFlex(®) Biliary RX fully and partially covered stents for the palliative treatment of malignant bile duct strictures. The WallFlex Biliary RX uncovered stent was cleared by the FDA in 2006. All three models of the WallFlex Biliary RX Stenting System -- fully covered, partially covered and uncovered -- are now available in both the United States and Europe.

"The WallFlex Biliary RX Stent System represents the next stage in self-expandable metal stent technology. The stent has greater flexibility to aid with placement in tortuous anatomies and new features such as flared ends that may reduce the risk of migration," said Kenneth F. Binmoeller, M.D., Director of Interventional Endoscopy at California Pacific Medical Center, and an investigator for the WallFlex Biliary RX fully covered stent study.

The WallFlex Biliary RX Stent is designed to offer the benefits of prior-generation stents, such as the industry-leading WALLSTENT(®) Endoprosthesis, while incorporating new features to accommodate a range of anatomical and clinical requirements. Based on extensive research and physician feedback, the WallFlex Biliary RX Stent employs a platinum-cored Nitinol construction designed to deliver on three critical components: radial force, flexibility and radiopacity. The Platinol™ Wire provides greater flexibility - 30 percent more than the WALLSTENT Endoprosthesis - to help the stent conform within tortuous anatomies. The enhanced full-length radiopacity offered by the Platinol Wire and the reconstrainable delivery system are designed to allow for more precise stent placement, while the radial force of the WallFlex Biliary RX Stent is designed to maintain patency and resist migration(1, 2).

TheWallFlex Biliary RX Stents also feature a closed-cell construction designed to resist tissue ingrowth(2), looped ends intended to reduce the risk of tissue trauma, and flared ends to help reduce the risk of stent migration. The proprietary, durable silastic polymer (Permalume(®)) covering of the fully and partially covered stents is designed to reduce the potential for tumor ingrowth. In addition, the WallFlex Biliary RX Stent incorporates an integrated retrieval loop for removal during the initial stent placement procedure, which can be used in the event of incorrect placement.

"Boston Scientific continues to fulfill our promise to deliver industry-leading, innovative technologies that enable physicians to best diagnose and treat digestive diseases, and enhance quality of life for patients," said Michael Phalen, President, Boston Scientific Endoscopy. "The WallFlex Biliary RX Stent leverages existing Boston Scientific technologies, while advancing performance with new features such as a unique Platinol Wire construction. We believe we are truly delivering the next generation of stents for the treatment of malignant bile duct strictures."

Preliminary results from Dr. Petersen's study were reported at United European Gastroenterology Week (UEGW) in 2008. Results showed that the fully covered WallFlex Biliary RX Stent yielded technically successful placement, low rates of re-intervention (two percent) and recurrent biliary obstruction, and minimal occurrence of migration (two percent) and complications. With 98 percent of patients meeting the primary endpoint of clinical palliation of the biliary obstruction until completion of follow-up, study results suggest that the fully covered WallFlex Biliary RX Stent may successfully palliate most patients with malignant distal biliary obstructions.

Also presented at UEGW were preliminary data on a 70-patient WallFlex Biliary RX partially covered stent study led by Primary Investigator Guido Costamagna, M.D., Head of Digestive Endoscopy at Universita Cattolica del Sacro Cuore in Rome. Preliminary results of the study demonstrate that the partially covered metal stent may palliate most patients with malignant biliary obstructions.

Pancreatic cancer is the most common cause of malignant biliary obstructions with 250,000 new cases diagnosed worldwide each year. Most patients have less than six months to live after diagnosis(3). Other causes of malignant biliary obstructions include bile duct, liver and gallbladder cancer. Approximately 70 percent of patients with a malignant bile duct obstruction are poor candidates for surgery because the cancer has spread (4). With these cases, palliative treatment can improve the patient's quality of life by controlling the symptoms

and complications of the disease.

The safety and effectiveness of the WallFlex Biliary RX Stenting System for use in the vascular system have not been established.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

About Boston Scientific Endoscopy

Boston Scientific Endoscopy develops innovative technology for less invasive, more efficient gastrointestinal procedures.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of 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 our product performance, regulatory approval of our products, competitive offerings, our growth strategy, and our market position. 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 thereafter. 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.

(1) Soderlund K., Linder S.; *Covered metal versus plastic stents for malignant common bile duct stenosis: a prospective, randomized, controlled trial*. Gastrointestinal Endoscopy, June 2006; 63: 986-995.

(2) Moss A.; Morris E.; MacMathuna P.; *Palliative biliary stents for obstructing pancreatic carcinoma*. Cochrane Database Systematic Review, January 25, 2006.

(3) Association for International Cancer Research, http://www.aicr.org.uk/PancreaticCancerFAQs.stm, August 17, 2009.

(4) Mahesh Kumar Neelala Anand, *Pancreas, Adenocarcinoma*.emedicine.com.

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