Boston Scientific

Boston Scientific Completes Enrollment in Benign Stricture Study of WallFlex® Biliary RX Stent

NATICK, Mass., Oct. 18, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has completed enrollment in a clinical trial to evaluate its WallFlex® Biliary RX Fully Covered Stent for the treatment of benign bile duct strictures (narrowing or blockages). This multi-center, prospective study enrolled 187 patients at 13 centers in 11 countries worldwide. Lead Investigators in the study are Professor Jacques Deviere, M.D., Ph.D., of Hospital Erasme in Brussels, and Professor Guido Costamagna, M.D., of Policlinico A. Gemelli in Rome.

The study includes patients with bile duct strictures associated with post liver transplant anastomosis (connection of two structures), prior abdominal surgery such as cholecystectomy (gall bladder removal) and chronic pancreatitis (inflammation of the pancreas). The WallFlex Biliary RX Fully Covered Stent will remain in patients five to 11 months depending on the nature of the stricture. The trial will evaluate the removal of the stents from patients as well as the effectiveness of temporary stenting for long-term benign biliary stricture resolution. Patients will be followed for five years after stent removal.

"This is a key milestone for this important trial," said Professor Deviere. "We look forward to the findings, which will determine the potential benefits of this stent as a less-invasive alternative to surgery in these types of patients and as an endoscopic treatment option that may require fewer ERCP(1) procedures than plastic stenting."

The WallFlex Biliary RX Stent is constructed of braided, Platinol™ (platinum-cored Nitinol) wire and features three key attributes: 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. The WallFlex Biliary RX family of stents is available in fully covered, partially covered and uncovered versions. Covered stents have a silicone polymer Permalume® Coating designed to reduce the potential for tumor ingrowth, and an integrated retrieval loop for removing or repositioning the stent during the initial procedure in the event of incorrect placement.

"The WallFlex Biliary RX Stent incorporates advanced features based on physician feedback to enhance its strength, deliverability and visibility," said David Pierce, President of Boston Scientific's Endoscopy Division. "Our WallFlex Biliary Stents complement our extensive line of enteral and esophageal stents to offer a complete range of treatment options to palliate and treat patients with gastrointestinal diseases."

The WallFlex Biliary RX Fully Covered, Partially Covered and Uncovered Stents are currently cleared in the U.S. and CE Mark countries for the palliative treatment of malignant bile duct strictures. The WallFlex Biliary RX Fully Covered Stent was CE Marked in 2010 for an expanded indication to treat benign biliary strictures. 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.

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 new product launches and launch cadence, regulatory approvals, clinical trials, product performance 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.

(1) Endoscopic Retrograde Cholangiopancreatography (ERCP) is a technique that combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems of the biliary or pancreatic ductal systems.

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