Boston Scientific

Boston Scientific Announces Enrollment of First Patient in Benign Stricture Study of WallFlex® Biliary RX Stent

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(NYSE:BSX)

NATICK, Mass. and DUSSELDORF, Germany, Jan. 14 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the first patient has been enrolled in a clinical trial to evaluate its WallFlex(®) Biliary RX Fully Covered Stent for the treatment of benign bile duct strictures. This multi-center, prospective study plans to enroll 187 patients at 11 centers(1) worldwide over the next 18 months. The first patient was enrolled by Professor Horst Neuhaus at the Evangelisches Krankenhaus in Dusseldorf, Germany. Lead Investigators in the study are Professor Jacques Deviere of Hospital Erasme in Brussels, and Professor Guido Costamagna of Policlinico A. Gemelli in Rome.

"We are pleased to have enrolled the first patient in this important trial to assess the WallFlex Biliary RX Fully Covered Stent as a potential option for the treatment of benign biliary strictures," said Professor Neuhaus. "The WallFlex Stent has proved to be effective in the management of malignant bile duct strictures, and the start of this trial represents a significant clinical milestone in determining optimal treatment strategies for patients with benign bile duct strictures."

The trial will evaluate the removal of the stents from patients with benign bile duct strictures as well as the effectiveness of temporary stenting for long-term, benign biliary stricture resolution. The study will include patients with bile duct strictures associated with post liver transplant anastomosis, prior abdominal surgery such as cholecystectomy (gall bladder removal) and chronic pancreatitis (inflammation of the pancreas). The WallFlex Biliary RX Stent will remain in the patients four to 12 months depending on the nature of the stricture. Patients will be followed for five years after stent removal.

"We believe this trial is the most comprehensive of its kind and is critical to advancing our knowledge of fully covered, self-expanding metal stenting as an endoscopic treatment for benign biliary strictures," said Professor Deviere. "Use of the WallFlex Biliary RX Fully Covered Stents in these patients may provide significant benefits as a minimally invasive alternative to surgery."

The WallFlex Biliary RX 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. The WallFlex Biliary RX family of stents is available in fully covered, partially covered and uncovered versions. The covered stents have a silicone polymer 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 start of patient enrollment in the WallFlex study is an important achievement for Boston Scientific, and we look forward to continuing enrollment in additional countries in the near future," said Michael Phalen, President, Boston Scientific Endoscopy. "The WallFlex Biliary RX Stent System was designed with physician feedback in mind, reinforcing our commitment to providing physicians with the world's leading technologies to treat and diagnose digestive diseases."

The WallFlex Biliary RX Stents have received U.S. Food and Drug Administration clearance and CE Mark approval and are indicated for the palliative treatment of biliary strictures produced by malignant neoplasms. 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, clinical trials, 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 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) Centers are in: Australia, Austria, Belgium, Canada, France, Germany, India, Italy, the Netherlands and Spain.

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