Boston Scientific Announces CE Mark Approval for Expanded Indication of WallFlex® Biliary RX Stent

Boston Scientific

NATICK, Mass., Oct. 22 /PRNewswire [1]/ -- Boston Scientific Corporation (NYSE: BSX) today announced that its WallFlex® Biliary RX Fully Covered Stent has received CE Mark approval for the treatment of benign biliary strictures.

"The WallFlex Biliary RX Fully Covered Stent has proved effective in the management of malignant biliary strictures, and I'm pleased that physicians in Europe and other CE Mark countries can now use this stent to treat benign biliary strictures," said Professor Jacques Deviere, M.D., Ph.D., Hopital Erasme in Brussels. "The WallFlex Stent incorporates the latest innovations in self-expanding metal stent technology and may provide significant benefits as a less-invasive alternative to surgery in these patients."

"This new indication gives me the confidence to perform what I have found to be the most effective therapy – metal stent placement – during the initial ERCP(1) procedure in patients where previously I would have waited for a confirmed diagnosis of the stricture," said Adrian Hatfield, M.D., University College London Hospital. "It may help to reduce the number of procedures my patients must undergo, while containing costs and providing the best possible care."

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. The covered stents have 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 up to 12 months following initial placement in benign strictures for the fully covered stents.

"The WallFlex Biliary RX Stent leverages existing Boston Scientific technologies, while advancing performance with new features based on physician feedback," said Michael Phalen, Senior Vice President, and President of Boston Scientific's Endoscopy Division. "With our full line of WallFlex Biliary, Enteral and Esophageal Stents, Boston Scientific offers the most comprehensive range of innovative treatment options to diagnose, palliate and treat patients with diseases of the gastrointestinal tract."

The complete line of WallFlex Biliary RX Stents -- Fully Covered, Partially Covered and Uncovered -- have previously received CE Mark and FDA clearance for the

palliative treatment of malignant biliary strictures. The WallFlex Stent is the most frequently implanted biliary metal stent worldwide.

Boston Scientific at UEGW

The WallFlex family of self-expanding metal stents will be available for hands-on demonstration at the United European Gastroenterology Week (UEGW), October 23 - 27 in Barcelona.

Boston Scientific will host a symposium titled "Controversies in Biliary Stenting," chaired by Professor Guido Costamagna, M.D., Policlinico Gemelli, Rome, which will take place on October 27 from 7:00 - 8:00 a.m. (local time) in the CCIB Congress Center, Room 112, Level 1. The symposium will include the following presentations:

- "Stenting for Benign Biliary Strictures: Whether, What and When?" by Professor Horst Neuhaus, M.D., Evangelisches Krankenhaus, Dusseldorf
- "Preoperative Therapy and Stenting: A Surgeon's Perspective," by Professor Mustapha Adham, M.D., Hopital Edouard Herriot, Lyon
- "A Metal Stent for Every Extrahepatic Biliary Stenosis?" by Professor Thierry Ponchon, M.D., Hopital Edouard Herriot, Lyon

The WallFlex Biliary RX Fully Covered Stent is not approved in the U.S. for the treatment of benign biliary strictures. The safety and effectiveness of the WallFlex Biliary RX Stent System for use in the vascular system have not been established.

(1) Endoscopic Retrograde Cholangiopancreatography

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 [2].

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 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, competitive offerings and 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.

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