Boston Scientific

Boston Scientific Announces FDA Clearance and CE Mark Approval for Advanix™ Biliary Stents

Latest innovation in plastic biliary stent technology includes features for enhanced deliverability, efficiency and procedural control

NATICK, Mass., Oct. 21 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration and CE Mark approval to market its Advanix™ Biliary Plastic Stents for the treatment of biliary strictures, including biliary stone disease, benign biliary strictures, and suspected and confirmed malignancies in the biliary system. The product is now available in Europe and other international markets; the Company plans to launch it in the U.S. this quarter.

Endoscopic therapy, specifically with stent placement, has gained acceptance as a first line of treatment for biliary strictures and offers a less-invasive alternative to surgery. Results from a published study of patients with post-operative benign bile duct strictures demonstrated that stenting has similar long-term success rates and lower early complication rates compared to surgery(1).

The Advanix Biliary Stent is designed to accommodate a range of clinical requirements and includes features for improved deliverability in navigating tortuous anatomy. It employs the NaviFlex™ RX Delivery System, which offers physicians the flexibility to employ both long-wire and short-wire guidewires during access and stent placement. The pre-loaded stent within the delivery system enables physicians to reposition the stent, helping to ensure accurate placement. The highly visible guidewire exit port allows for easier manipulation during the procedure.

"The Advanix Biliary Stent System features significant developments in plastic stent technology," said Stuart Sherman, M.D., Clinical Director of Gastroenterology and Hepatology, and Director of the ERCP(2) program at Indiana University Medical Center in Indianapolis. "Improvements in design provide greater procedural control and efficiency while navigating tight strictures in the bile ducts, facilitating stent placement and removal. The thin wall and increased inner diameter of the stent may provide extended patency of the duct, which could improve treatment outcomes."

"Boston Scientific remains committed to delivering innovation and leadership in endoscopic stent technology," said Michael Phalen, Senior Vice President, and President of Boston Scientific's Endoscopy Division. "The Advanix Biliary Stent System represents the latest advances in plastic stent design, enabling physicians to more efficiently and effectively treat blockages in the bile duct. In addition, it strengthens our broad stent portfolio and provides another solution for the ERCP suite."

Benign strictures in the bile duct are typically caused by prior surgical procedures, biliary stones or chronic pancreatitis, a disease in which digestive enzymes begin to break down and attack the pancreas. Chronic pancreatitis is extremely painful and in severe cases, can lead to infection, shock and respiratory failure. The most common cause of malignant biliary obstruction is pancreatic cancer, which is rarely diagnosed in the early stages, and is the second most common cause of death among gastrointestinal cancers. Other causes of malignant biliary obstructions include bile duct, liver and gallbladder cancer.

The Advanix Biliary Stent and NaviFlex RX Delivery System are available in a variety of sizes and shapes to accommodate both malignant and benign biliary strictures, distinct patient anatomies and physician preferences.

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 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.

1) Davids, P., M.D., et al, "Benign Biliary Strictures: Surgery or Endoscopy," *Annals of Surgery*, 1993; 217(3) 237-243.

2) Endoscopic Retrograde Cholangiopancreatography

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