Boston Scientific

Multi-Center Patient Registry Supports Safety and Clinical Utility of Boston Scientific's SpyGlass® Direct Visualization System

NATICK, Mass. and SAN DIEGO, May 20 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced results from an international, multi-center patient registry documenting favorable safety and clinical utility data for its SpyGlass® Direct Visualization System, which offers extensive visual access to the biliary tract. Results from the registry were presented by Yang K. Chen, M.D., Division of Gastroenterology & Hepatology, University of Colorado at Denver and Health Services Center and lead investigator, at Digestive Disease Week® (DDW) in San Diego. Two additional subset analyses from the SpyGlass patient registry were also presented at the conference.

The patient registry reports on clinical data from 296 patients at 15 medical centers (10 U.S. and 5 European sites) who required peroral cholangioscopy (PO) for stone therapy or investigation of suspected pathology with or without biopsy. Results of the study indicate that PO using the SpyGlass System can be safely performed by a single operator and provides reliable access to target sites for visual inspection and stone therapy. In addition, the SpyBite® Biopsy Forceps were found to obtain adequate histologic tissue specimens.

"The SpyGlass registry provides important information to physicians in assessing the safety and clinical effectiveness of the system," said Dr. Chen. "Preliminary results demonstrate that visual examination combined with directed tissue sampling using the SpyGlass System may improve accuracy of diagnosis in patients with indeterminate bile duct lesions."

The SpyGlass System is the first single-use direct visualization system that requires only a single physician operator and provides four-way steerability in a four lumen single-use catheter. The catheter provides two dedicated irrigation channels in addition to a 1.2 mm working channel through which diagnostic and therapeutic devices can be used in the biliary ducts. The system includes a miniature 6,000-pixel fiber optic probe attached to a camera that provides physicians with a direct view of a patient's bile ducts, overcoming some of the visual challenges of conventional endoscopic retrograde cholangiography procedures (ERCP).

As part of the international multi-center SpyGlass registry, Mansour Parsi, M.D., Department of Gastroenterology and Hepatology at the Cleveland Clinic, also reported on clinical data from 98 patients, demonstrating that peroral cholangioscopy using the SpyGlass System is safe and effective for the treatment of difficult-to-remove biliary stones. In addition, Dr. Parsi concluded that the rate of missed stones by an ERCP may be higher than previously reported and more research is required.

An additional subset analysis from the patient registry, led by Douglas Pleskow, M.D., Director, Colon Cancer Center and Co-Director, GI Endoscopy at Beth Israel Deaconess Medical Center in Boston, involved 136 patients with indeterminate biliary strictures or filling defects who underwent an ERCP followed by peroral cholangioscopy using the SpyGlass System and the SpyBite Biopsy Forceps. The study results indicate that targeted biopsies using the SpyGlass System are feasible and safe, and provide specimens adequate for histology in 89 percent of cases. Preliminary results also show that biliary biopsies obtained under direct visualization by peroral cholangioscopy using the SpyBite Biopsy Forceps can be useful in selected clinical situations including histologic confirmation of malignant or benign intrinsic lesions of the bile duct. Patient follow-up for this registry is ongoing.

"This multi-center registry adds to the growing body of evidence that supports the benefits of the SpyGlass System for single-operator duodenoscope-assisted cholangiopancreatoscopy in performing diagnostic and therapeutic endoscopic procedures such as targeted biopsies and the management of biliary stones," said Michael P. Phalen, President, Boston Scientific Endoscopy. "The SpyGlass System is making cholangioscopy feasible for physicians worldwide and improving the quality of healthcare for patients."

About Digestive Disease Week®

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 17-22, 2008, at the San Diego Convention Center, San Diego, CA. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit http://www.ddw.org/.

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: http://www.bostonscientific.com/.

About Boston Scientific Endoscopy

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

stand beside our physicians, surgeons and nurses, providing comprehensive support locally and through hands-on education and industry sponsorships, to help improve patient outcomes.

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, statements regarding clinical trials, regulatory approvals, competitive offerings, product performance 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.

CONTACT: Paul Donovan
508-650-8541 (office)
508-667-5165 (mobile)
Media Relations
Boston Scientific Corporation

Larry Neumann
508-650-8696 (office)
Investor Relations
Boston Scientific Corporation

SOURCE: Boston Scientific Corporation

CONTACT: Media, Paul Donovan, +1-508-650-8541 (office), +1-508-667-5165 (mobile), or Investors, Larry Neumann, +1-508-650-8696 (office), both of Boston Scientific Corporation

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