Boston Scientific

Four Clinical Studies Support Safety and Effectiveness of ENTERYX® Procedure in Treating GERD Symptoms

and Chicago, IL (May 18, 2005) -- Boston Scientific Corporation (NYSE: BSX) today announced results of four clinical trials demonstrating patient satisfaction with, and effectiveness of, the ENTERYX® Procedure in relieving the symptoms of gastroesophageal reflux disease (GERD). Results were presented in oral and poster sessions at the Digestive Disease Week® (DDW®) 2005 conference, held in Chicago May 14-19.

"These clinical trial results demonstrate the safety and efficacy of the ENTERYX Procedure at controlling GERD symptoms, and show that the ENTERYX Procedure contributes to high levels of patient satisfaction as compared to daily proton pump inhibitor (PPI) treatments," said Glen Lehman, M.D., Professor of Medicine and Radiology, Associate Director of Clinical Affairs, Department of Medicine, Indiana University Medical Center. "The growing body of clinical data suggests that the ENTERYX Procedure has a place in the treatment algorithm for chronic GERD sufferers."

"Boston Scientific is very pleased to present such a broad collection of data on the ENTERYX Procedure," said Steve Moreci, Boston Scientific Senior Vice President and Group President, Endosurgery. "These studies confirm the value of the ENTERYX procedure as a safe and effective treatment option for appropriate patients who suffer from chronic GERD symptoms. We are committed to providing the medical community with additional data from clinical trials."

Studies presented at DDW included the following key findings:

- **Patients were more satisfied and achieved better control of GERD symptoms with the ENTERYX Procedure than with PPI use.**

Reporting interim results from the study, **"GERD Symptoms and Treatment Satisfaction Among ENTERYX Patients" (Presentation # S1167)**, David Johnson, M.D., Professor of Medicine, Chief of Gastroenterology, Eastern Virginia School of Medicine, Norfolk, VA, showed that compared to proton pump inhibitor therapy (PPI) used prior to the ENTERYX Procedure, patients were more satisfied and achieved better control of their GERD symptoms with the ENTERYX Procedure according to satisfaction questions administered at baseline on PPIs and at study follow-up visits after ENTERYX treatment. Using a GERD-specific questionnaire, patients reported substantial improvement in GERD symptom control and relief, freedom to eat and drink, ability to sleep better and higher overall rates of treatment satisfaction with the ENTERYX Procedure compared to their prior experience on PPI medications. The study, which included follow-up assessments at one and six months following the ENTERYX Procedure, enrolled 322 patients in two post-market, multi-center studies. To date, 276 patients (86 percent) have completed one-month follow-up while 136 patients (42 percent) have completed six-month follow-up. Results for the 136 patients who completed the six-month follow-up show that the mean GERD-HRQL (Health Related Quality of Life) symptom score improved significantly from 19.4 at baseline to 9.6 at six months post-procedure ($p<0.0001$).

- **Nearly two-thirds of 46 patients were able to reduce or discontinue their PPI use as well as maintain GERD symptom control after three years.**

Presenting interim results from the study, **"Endoscopic Implantation of ENTERYX for the Treatment of GERD: 36-Month Follow-Up in 46 U.S. Subjects" (Presentation # 327),** Dr. Lehman reported PPI use for 46 patients who currently were available for evaluation. This multicenter, FDA-mandated, post-market study of 300 patients assessed safety and effectiveness of the ENTERYX Procedure at 36 months following treatment. At 36 months, 29 patients (63 percent) had reduced their PPI use by at least 50 percent, including 25 patients (54 percent) who had completely eliminated PPI use. Mean 36-month GERD-HRQL heartburn and regurgitation scores significantly improved ($p<0.0001$ for each) compared to baseline. No significant complications were reported between time of treatment and three-year follow-up.

- **Initial results from largest-ever, U.S.-based placebo-controlled trial for endoluminal GERD therapy show that the ENTERYX Procedure leads to improved pH scores - a key indicator of acid reflux.**

Presenting interim results from the study, **"Improved acid exposure and symptom scores 3 months post-ENTERYX: Initial U.S. randomized controlled trial results,"** Dr. Lehman reported on this multicenter, prospective trial, which is the largest randomized, controlled trial for any endoluminal GERD therapy to date. The study compared both objective (pH-metry) and subjective (GERD-HRQL) scores for patients undergoing the ENTERYX Procedure to those in a control group who received endoscopy and dimethyl sulfoxide (DMSO) solvent spray on the distal esophagus and proximal stomach. Results showed that at three months, the ENTERYX Procedure significantly improved scores for both measures as compared to a placebo-controlled procedure.

Interim analysis results at three months showed that, among the 62 patients (31 in the ENTERYX Procedure group and 31 in the control group) who were available for evaluation, 50 percent of the ENTERYX group versus 23 percent of the control group ($p<0.05$) were able to normalize or improve pH scores. In the ENTERYX group, 83 percent of patients achieved successful GERD-HRQL heartburn scores, defined as ≤11 or improved from baseline by >9 points, versus 54 percent of the control group ($p<0.05$). Mean change from baseline in pH-metry was -4.3 percent in the ENTERYX Procedure group vs. -0.5 percent in the

control group (p<0.05).

- **First placebo-controlled trial for the ENTERYX Procedure shows that more than two-thirds of 32 patients completely eliminated use of PPIs at three-month follow-up.**

- Final results for the European-based study, **"ENTERYX for the treatment of GERD: 12-month follow-up results of a randomized, sham-controlled, multicenter trial" (Presentation # 324),** presented by Jacques Devière, M.D., Professor of Medicine Chairman, Department of Gastroenterology and Hepatology, Erasme University Hospital, Universite Libre de Bruxelles, Brussels, Belgium and President-elect, European Society of Gastrointestinal Endoscopy compared PPI use for 32 patients who received an endoscopic injection of the ENTERYX Solution and 32 patients who underwent standard endoscopy in a European multi-center trial of 64 patients. Results were consistent with those from prior open-label studies of the ENTERYX Procedure and indicated that the response to the ENTERYX Procedure is not a placebo effect. After three months, 81 percent of patients undergoing the ENTERYX Procedure and 53 percent of the control group had reduced their PPI use by at least 50 percent (p<0.05). Additionally, 68 percent of ENTERYX patients and 41 percent of control-group patients had completely eliminated PPIs (p<0.05). 81 percent of subjects in the control group requested the ENTERYX Procedure after they learned that they were in the control group and were given the option for treatment. Follow-up with patients continued through 12 months after treatment. At 12 months, 70 percent of 20 ENTERYX patients were still off PPIs.

About GERD

Approximately 60 million people in the United States have GERD symptoms. Located between the esophagus and stomach is a muscular ring called the lower esophageal sphincter (LES). The LES acts as a valve to let food pass into the stomach and to keep stomach fluids and acids from backing up into the esophagus (reflux). For most people with GERD, the LES cannot completely close. Symptoms can include heartburn that is persistent, frequent and severe enough to disrupt patients' daily activities. The stomach fluids and acid that reflux into the esophagus can also irritate and damage the lining, perhaps leading to inflammation (esophagitis) or ulcers. This damage may scar and narrow the esophagus lining, which may make it hard or painful to swallow. In severe cases, the lining of the esophagus can change, possibly leading to cancer of the esophagus.

About the ENTERYX® Procedure

The ENTERYX Procedure is an outpatient procedure that typically takes less than one hour to complete. A physician passes a long, flexible tube called an endoscope through the patient's mouth and into the esophagus. The endoscope lets the physician see the lining of the patient

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