EndoGastric Solutions Announces Publication of Study Demonstrating Benefits of TIF Procedure in Controlling GERD Symptoms

Prospective, Randomized Study Showed Durability of Clinical Outcomes in the TIF Group and Improved Control of GERD symptoms in the Crossover Group

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SAN MATEO, Calif.--(BUSINESS WIRE)--EndoGastric Solutions® (EGS), a leader in endoluminal reconstructive treatment for gastroesophageal reflux disease (GERD), announces publication of one-year results of the TEMPO randomized, crossover trial, which found that the Transoral Incisionless Fundoplication (TIF®) procedure achieved sustained elimination of all GERD symptoms and healing of esophagitis.

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In the patients randomized to the TIF treatment group (n=39), 93% achieved elimination of troublesome regurgitation; 77% achieved global elimination of all atypical symptoms and regurgitation. Reflux esophagitis was healed in all 19 patients who presented with the erosive disease on PPI therapy before the TIF procedure. Ninety-seven percent of patients were off daily PPI therapy. All esophageal pH parameters were significantly reduced at 12-month follow-up, compared to baseline.

In the crossover (control) group (n=21), after six months of high-dose PPI therapy twice daily, only 5% (1/21) of patients reported global elimination of regurgitation and atypical symptoms; this proportion significantly increased to 65% (13/20) six months after these patients crossed over and had the TIF procedure. Additionally, 80% of the cross-over patients were off daily PPIs six months following the TIF procedure.

"Approximately 30-40% of GERD patients remain symptomatic on PPI therapy," said Karim S Trad, MD TEMPO principal investigator and a surgeon at George Washington University School of Medicine and Health Sciences. "This randomized trial demonstrates the ability of the TIF procedure to provide dramatic symptomatic relief and healing of reflux esophagitis in patients who present with significant clinical challenges. Based on the results of this study, we can now offer these patients an endoluminal, less invasive approach to relieve their troublesome GERD symptoms."

"We are thrilled that the results of this study have confirmed that the TIF procedure is significantly more effective than high-dose PPI therapy in relieving troublesome regurgitation and atypical GERD symptoms," said Skip Baldino, EGS President and CEO. "This is the only incisionless procedure currently available in the US that reconstructs a defective

gastroesophageal valve with an endoscopic approach that is supported by safety and effectiveness data from randomized trials."

The primary outcome of TIF® versus Medical PPI Management of Refractory GERD symptoms (TEMPO) trial was elimination of daily troublesome regurgitation and atypical symptoms as evaluated by two validated instruments—Reflux Disease Questionnaire and Reflux Symptom Index; secondary outcomes included healing of esophagitis, normalization of esophageal acid exposure and PPI use in the TIF treated patients at six and 12 months.

The results were published in the *BioMed Central (BMC) Gastroenterology.* This data include results from 60 patients treated at seven U.S. centers, including three gastroenterology practices and four general surgery practices. Abstract is available here: http://www.gerdhelp.com/gerd-references/.

About GERD

Gastroesophageal Reflux Disease (GERD) is a chronic condition in which the gastroesophageal valve (GEV) allows gastric contents to wash back up into the esophagus, causing heartburn and possible injury to the esophageal lining. The stomach produces hydrochloric acid and other digestive enzymes after a meal to aid in the digestion of food. The cells that line the stomach compose a protective mucus that can withstand gastric contents, while the cells that line the esophagus lack the same protection.

GERD is the most common gastrointestinal-related diagnosis made by physicians during clinical visits in the U.S. It is estimated that pain and discomfort from acid reflux impacts over 23 million people two or more times per week in the U.S. The standard recommendations for symptomatic GERD patients include lifestyle changes (e.g. diet, scheduled eating times, and sleeping positions) and escalating doses of prescription medications for prolonged periods of time. Long-term, maximum dose usage of prescription medications has been linked to a variety of other health complications.

About the EsophyX® device

The EsophyX device was FDA cleared in 2007, and is commercially available in the United States. Inserted through the patient's mouth with visual guidance from an endoscope, the EsophyX device is used to reconstruct the gastroesophageal valve (GEV) in order to restore its function as a barrier to prevent stomach acids from washing back up into the esophagus.

About Transoral Incisionless Fundoplication (TIF®) procedure for reflux

Performed entirely through the mouth without the need for external incisions through the skin, the TIF procedure offers patients who require an anatomical change to correct the underlying cause of GERD, another treatment option beyond traditional surgery. Studies show that for up to three years after the TIF procedure esophageal inflammation (esophagitis) is eliminated and most patients are able to stop using daily PPI medications to control symptoms.

The TIF procedure has an established safety and efficacy profile with more than 15,500 patients treated worldwide. For more information, visit **www.GERDHelp.com.**

About EndoGastric Solutions®

EndoGastric Solutions, Inc. (**www.endogastricsolutions.com**), headquartered in San Mateo, California, is a leader in the endoluminal treatment of digestive diseases. EGS' mission is to combine the most advanced concepts in gastroenterology and surgery to develop products and procedures that address unmet needs in gastrointestinal diseases.

The EsophyX device with SerosaFuse fasteners is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

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