EndoGastric Solutions Announces New Sham-Controlled European Study Demonstrates Transoral Incisionless Fundoplication (TIF) Procedure as Effective Alternative for Daily PPI Treatment

Study Found 59% of Patients Undergoing TIF Procedure Had Remission of Gastroesophageal Reflux Disease Symptoms after Six Months

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REDMOND, Wash.--(BUSINESS WIRE)--EndoGastric Solutions® (EGS), a leader in incisionless procedural therapy for gastroesophageal reflux disease (GERD), today announced findings published online by *Alimentary Pharmacology and Therapeutics* from a new double-blind, sham-controlled, multi-center European study, which further confirmed the efficacy of the company's Transoral Incisionless Fundoplication (TIF®) procedure as a viable alternative to proton pump inhibitors (PPIs) to control chronic symptoms of GERD.

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Prior to the TIF procedure, patients were required to refrain from PPI consumption for at least 10 days. Of the randomized patients treated with the TIF procedure, 59% were determined to be in remission after six months compared to 9% of patients in the sham treatment arm ($p < 0.0001$).

The study also reported TIF procedure patients had improved acid reflux time (measurements of esophageal acid exposure) from 8.89 to 3.73 ($p = 0.0002$) compared to the sham-controlled group which had no changes in acid reflux time.

"It can now be concluded that Transoral Incisionless Fundoplication (TIF2) offers chronic GERD patients, being on long-term treatment with PPI, an effective therapeutic alternative," stated Lars Lundell, MD, lead investigator of the study and Professor of Medicine at Karolinska University, Huddinge Hospital, Stockholm. "In fact, we can also conclude that the level of scientific proof of its efficacy and therapeutic gain surpasses anything that is available outside the area of traditional laparoscopic anti-reflux therapy."

This is the second randomized study using a sham-controlled group that was conducted on a demographically balanced and diverse body of 44 patients between 18 and 80 years old. Originally, from 406 initial contacts, 121 patients were screened who suffered from persistent GERD symptoms and relied on daily administration of PPIs for relief for at least six months prior to enrollment.

The paper "Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD" can be found here [http://www.gerdhelp.com/blog/references/randomised-clinical-trial-transoral-incisionless-fundoplication-vs-sham-intervention-to-control-chronic-gerd/] and a poster will be on display at United European Gastroenterology's Week (UEGW) Conference in the Oesophageal, Gastric and Duodenal Disorders Section 1, October 26, 2015 09:00 to 17:00 local time at Fira de Barcelona - Gran Via Venue in Barcelona, Spain.

"This data is a new addition to the body of high quality TIF procedure evidence—it's the fourth randomized controlled trial and second sham-controlled study," said Skip Baldino, President and CEO of EGS. "This data aligns with RESPECT—our first sham-controlled study. In a recent New England Journal of Medicine editorial,[1] the medical device industry was challenged to conduct more sham

controlled trials in order to validate novel procedures and devices; Dr. Lundell's study has also met this most rigorous scientific test."

About GERD

Gastroesophageal reflux disease (GERD) is a chronic condition in which the gastroesophageal valve (GEV) allows gastric contents to reflux (wash backwards) 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 are coated with 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 80 million people at least once per month 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 Transoral Incisionless Fundoplication (TIF®) procedure for reflux

Performed without the need for external incisions through the skin, the TIF procedure offers patients who require an anatomical repair another treatment option to correct the underlying cause of GERD. 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.

Over 17,000 TIF patients have been treated worldwide since EsophyX® device clearance in 2007. More than 50 peer-review papers from over 40 centers have been published documenting consistent outcomes on over 800 unique study patients. For more information, visit www.GERDHelp.com.

About EsophyX® technology

The original EsophyX device was cleared by the FDA in 2007. EGS launched the third generation EsophyX device, the EsophyX Z in 2015. The technology has continued to evolve and is a clinically-backed tool for physician use in the treatment of GERD. The EsophyX technology now enables surgeons and gastroenterologists to use a wider selection of endoscopes–including low profile and larger high-definition models—to treat the underlying anatomical cause of GERD. The EsophyX technology is used to reconstruct the gastroesophageal valve (GEV) and restore its function as a barrier, preventing stomach acids refluxing back into the esophagus. The device is inserted through the patient's mouth with direct visual guidance from an endoscope.

About EndoGastric Solutions®

Based in Redmond, WA, EndoGastric Solutions, Inc. (www.endogastricsolutions.com), is a medical device company focused on developing and commercializing innovative, evidence-based, incisionless surgical technology for the treatment of gastroesophageal reflux disease (GERD). EGS has combined the most advanced concepts in gastroenterology and surgery to develop the Transoral Incisionless Fundoplication (TIF®) procedure—a minimally invasive solution that addresses a significant unmet clinical need.

Indications:

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.

References:

[1]Redberg, MD, R.F; Sham Controls in Medical Device Trials; N Engl J Med. 2014 Sep 4;371(10):892-3. http://www.nejm.org/doi/full/10.1056/NEJMp1406388

Contacts

Lazar Partners, LTD
Dawn Fallon, 646-871-8481 (direct)
dfallon@lazarpartners.com
or
EndoGastric Solutions, Inc.
Debbie Donovan, 408-621-0126 (cell)
ddonovan@endogastricsolutions.com

Twitter: **@GERDHelp**
Facebook: **GERDHelpcom**
Google+: **GERDHelp**