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Torax Medical Completes 5 Year Clinical Trials Affirming Long-term Benefits of Novel Procedure to Treat Gastro-esophageal Reflux Disease

St. Paul, Minn. (October 6th, 2014) Torax Medical announced today the forthcoming completion of a second 5-year clinical trial for the LINX procedure to treat gastro-esophageal reflux disease (GERD). Previous reporting of safety and efficacy for this pivotal trial provided the scientific evidence necessary for FDA approval for the LINX device in early 2012.

“Completion of this pivotal trial is a momentous achievement for the study investigators. The vigilance necessary to perform a study of this magnitude is significant and critical for the advancement of minimally invasive surgery,” commented Dr. Tom R. DeMeester, Chairman of the Medical Advisory Board for Torax Medical and Chairman Emeritus, USC Department of Surgery. Dr. DeMeester further stated, “This new data provides an essential basis for the long-term durability of the LINX procedure. GERD is a chronic condition and needs a minimally invasive treatment option like LINX, when the disease becomes progressive.”

Torax Medical’s LINX[®] Reflux Management System was studied as an Investigational Device Exemption (IDE), under regulatory oversight of the FDA, starting in 2007. The multi-center, prospective, pivotal trial was statistically powered to establish scientific evidence of safety and efficacy of the LINX procedure in the treatment of chronic reflux disease. Patients included in the pivotal trial were refractory to proton-pump inhibitor (PPI) therapy and had pathologic levels of esophageal acid exposure. The long-term efficacy endpoints evaluated at 5-years were control of reflux related symptoms and reduction in dependence of PPI therapy. Preliminary assessment of these endpoints, with over 80% of available patients reporting, showed that 86% of patients continue to have significant reduction in their reflux symptoms and 86% have eliminated their daily dependence on PPI therapy. These results are consistent with the [3-year clinical outcomes](#) previously reported from this study in the New England Journal of Medicine. This data along with additional peer-reviewed publications, including a [safety analysis of over 1,000 patients](#) confirm the clinical benefits and safety of the LINX procedure.

Todd Berg, President and CEO for Torax Medical said, "Torax Medical and physician thought leaders have now collaborated for over a decade building a foundation of evidence to support the safety and

efficacy of the LINX procedure. Top U.S. medical journals have already reported on over 1,000 unique patients treated with the LINX procedure. This 5-year pivotal study is an excellent capstone to this effort. Today, we are excited to see the LINX procedure offered in more than 200 medical centers, and are expanding this number monthly as new centers complete the LINX training program."

The Disease

Gastro-esophageal Reflux Disease (GERD) is a chronic, often progressive disease resulting from a weak lower esophageal sphincter that allows harmful gastric fluid to reflux into the esophagus, resulting in both pain and injury to the esophageal lining. Symptoms of GERD include heartburn and regurgitation, often associated with chronic sleep disruption, and may also include persistent cough, excessive throat clearing, hoarseness and a feeling of a "lump" in the throat. Acid reflux medications, such as Prevacid®, Nexium®, and Prilosec®, affect gastric acid production, but do not repair the sphincter defect, allowing continued reflux. Anti-reflux surgery called Nissen Fundoplication reconstructs a new reflux barrier using a portion of the patient's stomach which is wrapped around the lower portion of the esophagus. GERD is associated with a pre-cancerous condition known as Barrett's esophagus, which increases the risk of esophageal cancer.

The LINX Reflux Management System

LINX is a small implant comprised of interlinked titanium beads with magnetic cores. The magnetic attraction between the beads augments the existing esophageal sphincter's barrier function to prevent reflux. The device is implanted using a standard minimally invasive laparoscopic procedure and is an alternative to the more anatomically disruptive fundoplication, commonly used in surgical anti-reflux procedures. The LINX Reflux Management System is indicated for those patients diagnosed with GERD as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum medical therapy for the treatment of reflux.

LINX does require a surgical procedure and is associated with potential risks, contraindications and life style modifications. For more information on LINX, including a statement of risks, please visit www.linxforlife.com.

About Torax Medical

Torax Medical, Inc. is a privately-held medical device company headquartered in St. Paul, Minnesota that develops and markets products designed to treat sphincter disorders utilizing its technology platform, Magnetic Sphincter Augmentation (MSA). Torax Medical is currently marketing the LINX® Reflux Management System for the treatment of GERD in the U.S. and Europe and the FENIX™ Continence Restoration System for the treatment of Fecal Incontinence (FI) in Europe. For more information, please visit www.toraxmedical.com.

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