FDA Approves LINX® System for the Treatment of Reflux Disease

ST. PAUL, MINNESOTA – March 27, 2012 – Torax Medical today announced that the U.S. Food and Drug Administration (FDA) approved the LINX® Reflux Management System for use in patients diagnosed with Gastroesophageal Reflux Disease (GERD).

President and CEO of Torax Medical, Todd Berg, stated, “After years of extensive development and clinical studies, we are pleased to have the LINX System available to patients in the U.S. suffering from GERD. Torax will immediately begin training new centers throughout the U.S. We will work with medical centers that have a specific expertise in the treatment of reflux disease to create ‘Centers of Excellence’ for the LINX System. Patients will have access to the LINX procedure within the next 30 days.”

The LINX System
The LINX System 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 with a standard minimally invasive laparoscopic procedure.

“The approval of the LINX System represents an important step forward in the treatment of reflux disease. Today, patients who are refractory to acid suppression drugs have very limited options. This FDA approval is the culmination of over 5 years of clinical study and we are happy to have this treatment now available for our patients,” quoted Dr. Santiago Horgan, Professor and Chief, Division of Minimally Invasive Surgery, University of California, San Diego.

Dr. Tom DeMeester, Chairman Emeritus of Surgery USC Keck School of Medicine, further commented, "Chronic gastroesophageal reflux is a serious and progressive disease primarily resulting from a defect in the lower esophageal sphincter. I am impressed with the extensive clinical study of the LINX System which resulted in a unanimous recommendation for approval by a FDA Advisory Panel, followed now by FDA approval. The LINX System is a needed alternative to the current surgical anti-reflux procedure, Nissen fundoplication, originally developed over 50 years ago."

“The FDA’s process to approve the LINX System has been rigorous and thorough. We are pleased to be able to offer an innovative and much needed medical device option to patients and their healthcare providers for treatment of the debilitating symptoms of this disease,” noted Timothy Mills, Ph.D., Chairman of Torax Medical and Managing Director, Sanderling Ventures.

The Disease
Gastroesophageal 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.
Symptoms of GERD include heartburn, regurgitation, inability to sleep and dietary constraints. Acid suppression drugs, such as Prevacid®, Nexium®, and Prilosec®, affect gastric acid production but do not repair the sphincter defect and allow continued reflux. Reflux can progress to a pre-cancerous condition known as Barrett’s esophagus and possibly esophageal cancer. Approximately 7% of adults in western countries suffer daily from symptoms of GERD.

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 both the LINX Reflux Management System for the treatment of GERD and its FENIX™ Continence Restoration System for the treatment of Fecal Incontinence (FI) in Europe. Investors include: Sanderling Ventures, Thomas, McNerney & Partners, Accuitive Medical Ventures, Kaiser Permanente Ventures, and Mayo Medical Ventures. For more information, please visit www.toraxmedical.com.

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