TELA Bio Initiates BRAVO Study of OviTex™ for Hernia Repair

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Study to evaluate performance of OviTex Permanent 1S for treatment of ventral hernias.

MALVERN, Pa., April 25, 2017 /PRNewswire/ -- TELA Bio, Inc., a surgical reconstruction company leading the development and commercialization of Reinforced BioScaffolds (RBSs) for soft tissue repair, today announced the company has initiated a post-market clinical study, BioScaffold Reconstruction of Abdominal wall and Ventral hernia defects with Open or laparoscopic repair (BRAVO), of its OviTex™ Permanent 1S device.

OviTex RBSs represent the next step in hernia repair, integrating polymer and biologic materials in a unique embroidered construction. The biologic material, derived from ovine rumen, allows for functional tissue remodeling, while the polymer provides additional strength and improved handling. OviTex devices are available with either polypropylene polymer (permanent) or polyglycolic acid polymer (resorbable). TELA Bio commercialized OviTex RBSs in July 2016 and has completed over 400 implantations to-date in a wide range of hernia patients using a variety of surgical techniques.

"We are committed to providing surgeons with the advanced soft tissue repair materials they need, and that means we must continue to innovate and tailor OviTex products based on real-world experience," said Maarten Persenaire, MD, chief medical officer of TELA Bio. "Surgeon feedback on OviTex performance and surgical handling has been positive so far, and we are excited to initiate a formal clinical data collection program that will support future efforts to refine surgical mesh design and develop new clinical protocols for hernia repair."

The single-arm, prospective BRAVO study is designed to evaluate the clinical performance of OviTex Permanent 1S in 100 ventral hernia patients. Investigators will initially monitor the incidence of early post-operative surgical site occurrences, wound-related events, and other complications within the first three months following surgery. Further endpoints include the incidence of true hernia recurrence at 90 days, 12 months, and 24 months follow-up and post-operative surgical site occurrences and other complications occurring more than three months after surgery. In addition, patient reported outcomes such as quality of life and pain assessments will also be evaluated.

"Many of the biologic materials available today have the flexibility I need, but lack consistent long-term durability that is required for success in soft tissue reconstruction," said principal investigator George DeNoto III, MD, FACS, director of general surgery at St. Francis Hospital in New York. "OviTex RBSs are an exciting advance because they feature the benefits of both polymer and biologic materials, strength and safety in one. I applaud this young company for taking the right approach to post-market research."

The first patient in the BRAVO study enrolled at Scripps Clinic in La Jolla, California.

"We are pleased to be the first clinical site to enroll a patient in the post-market study," said Salvatore Pacella, MD, MBA, FACS, division head of plastic and reconstructive surgery at Scripps Clinic and Scripps Green Hospital in La Jolla, California. "OviTex RBSs are a promising new technology for hernia repair and we look forward to learning more about how this mesh design can impact the lives of our patients."

About TELA Bio, Inc.

TELA Bio, Inc. is a privately-owned company focused on bringing innovative, cost-effective, surgical reconstruction solutions to surgeons, hospitals and patients. The company's OviTex Reinforced BioScaffolds (RBSs) products, designed for hernia repair and abdominal wall reconstruction procedures, integrate polymer and biologic materials in a uniquely embroidered construction using novel engineering design principles. The OviTex portfolio is supported by high-quality, data-driven science and extensive pre-clinical research that has consistently demonstrated the advantages of an RBS over commercially available products. OviTex RBSs are commercially available in the U.S., and TELA Bio plans to launch OviTex RBSs in the European Union. The company is collaborating with leading surgeons to drive rapid product development and establish TELA Bio as a leader in surgical reconstruction. To learn more about TELA Bio visit http://www.telabio.com.

About OviTex Reinforced BioScaffolds

OviTex Reinforced BioScaffolds (RBSs) are intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.

Do not use OviTex RBSs in patients known to be sensitive to materials of ovine (sheep) origin. For additional important safety information, please see the OviTex RBSs Instructions for Use.

Caution: Federal (US) law restricts this device to sale by or on order of a physician.

TELA Bio, Inc. owns or has applied for the following trademarks or service marks: OviTex, TELA Bio.

Media contact

Adam Daley
Berry & Company Public Relations
212-253-8881
adaley@berrypr.com

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