TELA Bio® Announces Initial Data from BRAVO Study of OviTex® for Ventral Hernia Repair

June 7, 2018

Early outcomes from post-market clinical study presented at Abdominal Wall Reconstruction Conference in Washington, DC.

MALVERN, Pa., June 7, 2018 /PRNewswire/ -- TELA Bio®, Inc., a surgical reconstruction company leading the development and commercialization of OviTex® Reinforced BioScaffolds (RBSs) for soft tissue repair, today announced that early outcomes from the company's post-market BRAVO (**B**ioScaffold **R**econstruction of **A**bdominal wall and **V**entral hernia defects with **O**pen or laparoscopic repair) study evaluating OviTex 1S Permanent for the treatment of ventral hernias are being presented at the 2018 Abdominal Wall Reconstruction Conference taking place June 7 – 9 at the Grand Hyatt Washington in Washington, DC.

In the single-arm, prospective BRAVO study, investigators are monitoring the incidence of early post-operative surgical site occurrences (SSOs) or wound-related events occurring at the hernia repair site, complications, and recurrences, as well as conducting quality of life and satisfaction assessments. The initial data presented includes the first 24 patients who reached 90 day follow-up in the study. Seven patients experienced SSOs that were related to the type of surgical procedure performed, however none required surgery or removal of implant, and resolved at the time of analysis. To date, no subject has experienced a recurrence. The patient and surgeon satisfaction with the hernia repair are high.

"Our first analysis of prospective data from the BRAVO study suggests that OviTex is at least as effective as other biologic or resorbable implants," said principal investigator George DeNoto III, MD, FACS, director of general surgery at St. Francis Hospital in New York. "We look forward to continuing follow-up with patients in this important study evaluating a novel surgical implant."

TELA Bio first commercialized OviTex RBSs in July 2016. They are a distinct class of surgical implants that integrate biologic and synthetic materials in a unique embroidered construction that allows movement of fluid and cells through the construct. Over 2,000 implantations have been completed to date in a wide range of hernia procedures using a variety of surgical techniques.

"We are committed to continuously study and evaluate our portfolio of next generation products for soft tissue repair and help achieve improved patient care and surgical outcomes while reducing costs," said Maarten Persenaire, MD, CMO of TELA Bio. "The initial results from our post-market study are in line with the enthusiastic and nuanced feedback we are receiving from surgeons who already have implemented the use of OviTex in hernia repair procedures across the U.S."

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.

The statements made or results achieved by TELA Bio customers described herein were achieved in their specific setting. Due to variations in clinical experience and technique, there is no guarantee that these results are typical. Bench testing may not be indicative of clinical performance.

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.

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