TELA Bio Announces Results from Retrospective Study of OviTex® for Abdominal Wall Reconstruction

March 12, 2018

Data presented at Americas Hernia Society International Hernia Congress 2018 show low recurrence and complication rates.

MALVERN, Pa., March 12, 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 data from a retrospective study evaluating the use of RBSs in abdominal wall reconstruction (AWR) procedures show low recurrence and complication rates. The results are being presented at the Americas Hernia Society (AHS) International Hernia Congress 2018 held March 12-15 at the Fontainebleau Miami Beach in Florida.

OviTex RBSs integrate biologic and synthetic materials in a unique embroidered construction that allows free movement of fluid and cells through the construct. The biologic material, derived from ovine rumen, allows for functional tissue remodeling, while the polymer provides additional strength and improved handling.

Michael Sawyer, MD, FACS, general surgeon at Comanche County Memorial Hospital, conducted a retrospective chart review for a consecutive series of 14 patients undergoing AWR with OviTex RBSs used for reinforcement between June 2016 and November 2017. Recurrence rates, and rates of surgical site infection and other surgical site occurrences were analyzed as primary endpoints. Results from the study show a low recurrence rate (7.1%) and low complication rate (14.3%) at average follow up of about one year.

"AWR for complex incisional hernias is a challenging surgical task, and the repairs require reinforcement for durability and to decrease the incidence of recurrence," said Dr. Sawyer. "Synthetic and biologically derived reinforcement materials have their own inherent strengths and weaknesses. OviTex RBSs possess properties of both, representing a new paradigm in repair reinforcement that may improve patient outcomes and warrants longer-term study."

TELA Bio first commercialized OviTex RBSs in July 2016 and over 1,700 implantations have been completed to-date in a wide range of hernia procedures using a variety of surgical techniques. The company has initiated a post-market clinical study, BioScaffold Reconstruction of Abdominal wall and Ventral hernia defects with Open or laparoscopic repair (BRAVO).

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.

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