



TELA Bio® Announces Plans to Launch OviTex® in Europe

June 1, 2018

Distinct class of surgical implants for hernia procedures to launch in Europe

MALVERN, Pa., May 31, 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 its partner Aroa Biosurgery, a soft-tissue repair company based in New Zealand that develops and manufactures medical products to improve healing, has been granted EC Certification (CE Mark) allowing for the commercial launch of OviTex RBSs in the European Union (EU).

"We are excited to announce that our strategic partner has received a CE Mark for OviTex RBSs and look forward to bringing the benefits of this innovative solution to the European market," said Antony Koblisch, president and CEO of TELA Bio. "Historically, biologic products have had limited success in Europe due to their high price points, but our unique supply chain enables us to deliver OviTex RBSs at a significant cost reduction that is well-suited for the healthcare landscape overseas."

"Securing EC Certification will provide the opportunity for patients with complex hernia in Europe to gain access to the advantages of OviTex RBSs," said Brian Ward, CEO of Aroa Biosurgery. "We are pleased that TELA Bio can now build on their growing success in the United States and begin a commercial rollout in Europe."

TELA Bio first commercialized OviTex RBSs in the U.S. for ventral hernia repairs and abdominal wall reconstruction procedures in July 2016. They are a distinct class of surgical implants that integrate biologic and synthetic materials in a uniquely embroidered construction that allows 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.

More than 2000 implantations with OviTex RBSs have been completed to date in a wide range of hernia procedures using a variety of surgical techniques. Data from a retrospective study presented at the Americas Hernia Society International Hernia Congress 2018 showed the use of OviTex RBSs in abdominal wall reconstruction procedures led to low recurrence and complication rates.¹ TELA Bio has initiated a post-market clinical study, **BioScaffold Reconstruction of Abdominal wall and Ventral hernia defects with Open or laparoscopic repair (BRAVO)**, to further evaluate the safety and efficacy of OviTex RBSs.

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.

About Aroa Biosurgery

Aroa is a private, venture funded soft-tissue repair company that develops and manufactures medical products to improve healing. Its products are developed from their *Endoform*™ platform, a novel extracellular matrix biomaterial. Their portfolio includes products for wound care and soft tissue construction. The company strives to improve patient outcomes and provide better healing, every day, everywhere for everybody. www.aroabio.com

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¹ Presented at Americas Hernia Society (AHS) International Hernia Congress 2018, "Abdominal Wall Reconstruction with a New Ovine Polymer-

Reinforced Bioscaffold: Early Clinical Experience."

SOURCE TELA Bio, Inc.

Related Links

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