TELA Bio Announces Publication of Results from In-Vivo Study Demonstrating Favorable Response to Reinforced Biologics in Hernia Repair

February 4, 2020

MALVERN, Pa., Feb. 04, 2020 (GLOBE NEWSWIRE) -- TELA Bio, Inc. (“TELA”) (Nasdaq: TELA), a commercial stage medical technology company focused on designing, developing and marketing a new category of tissue reinforcement materials to address unmet needs in soft tissue reconstruction, today announced data from a non-human primate study demonstrating favorable response to reinforced biologic material used in a hernia repair compared to seven clinically used biologic and synthetic products. The data are published online in the journal, *Hernia*, the world journal of hernia and abdominal wall surgery, in an article entitled “In-vivo evaluation of a reinforced ovine biologic: a comparative study to available hernia mesh repair materials.” *Hernia* is published in cooperation with the American Hernia Society, the European Hernia Society, the Americas Hernia Society, and the Asia Pacific Hernia Society.

The study is the first of its kind to compare a wide variety of commercially used biologic, reinforced biologic and synthetic hernia repair materials in an animal model to predict clinical performance. The study used adult non-human primates, a species that shares greater than 98% of its DNA with humans and thus provides the best possible model to predict the response of the human immune system and healing kinetics.

In the study, two innovative reinforced biologics, OviTex 1S® Resorbable and OviTex 1S® Permanent, were studied in a non-human primate hernia repair model and were evaluated for their biologic performance as measured by inflammatory response, healing kinetics, integration, and remodeling into functional host tissue. For comparison, seven clinically used biologic and synthetic meshes were also studied. Seventy-three non-human primates were implanted with test articles in surgically created full thickness midline abdominal wall defects. Clinical observations were recorded daily. Implants were recovered at 4, 12, and 24 weeks and evaluated for signs of herniation, inflammation, adhesions, contraction, or other abnormalities as well as evidence of healing and integration.

The results showed that both the reinforced biologics (OviTex 1S®) and biologics remodeled into naturally appearing tissue and were associated with low levels of inflammation. However, reinforced biologics showed earlier cellular and blood vessel infiltration than biologics. This resulted in earlier remodeling and better maintenance of the geometry of the repair. In contrast, a foreign body response persisted with the synthetic mesh products which manifested itself as a layer of reactive tissue often above and separate from the contracted mesh structure.

“The data generated from this animal study were a critical tool for us to evaluate and confirm our design concepts prior to human implantation,” said Maarten Persenaire, M.D., co-founder, Chief Medical Officer of TELA Bio. “In the clinic, chronic inflammation associated with synthetic mesh can lead to serious complications including mesh erosion, contraction, chronic pain and infection. While biologic implants avoid the issue of chronic inflammation, they are prone to stretching over time. Based on the observed performance of the different products, we believe OviTex will address many of the concerns associated with the continuous foreign body response of synthetics and the stretching of biologics. In addition, the earlier host cell infiltration and remodeling may help explain the resilience of reinforced biologics against post-operative infections as has been reported by several surgeons.”

About TELA Bio, Inc.

TELA Bio, Inc. is a commercial stage medical technology company focused on designing, developing and marketing a new category of tissue reinforcement materials to address unmet needs in soft tissue reconstruction. TELA’s products are designed to improve on shortcomings of existing biologics and minimize long-term exposure to permanent synthetic material. TELA's portfolio is supported by quality, data-driven science and extensive pre-clinical research that has consistently demonstrated advantages over other commercially available products.

Caution Regarding Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Words such as “may,” “might,” “will,” “should,” “believe,” “expect,” “anticipate,” “estimate,” “continue,” “predict,” “forecast,” “project,” “plan,” “intend” or similar expressions, or statements regarding intent, belief, or current expectations are forward-looking statements and reflect the current beliefs of TELA’s management. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and other factors that could cause actual results and events to differs materially and adversely from those indicated by such forward-looking statements including, among others: our ability to gain market acceptance for our products and to accurately forecast customer demand, our ability to enhance our product offerings, development and manufacturing problems, capacity constraints or delays in production of our products. These and other risks and uncertainties are described more fully in the “Risk Factors” section and elsewhere in our filings with the with the Securities and Exchange Commission and available at www.sec.gov, including in our prospectus dated November 7, 2019. Any forward-looking statements that we make in this announcement speak only as of the date of this press release, and TELA assumes no obligation to updates forward-looking statements whether as a result of new information, future events or otherwise after the date of this press release, except as required under applicable law.

TELA Bio Contact
Stuart Henderson
Vice President, Corporate Development and Investor Relations
TELA Bio, Inc.
484-320-2930
shenderson@telabio.com

Investor Contact
Peter Vozzo
Westwicke
443-213-0505
peter.vozzo@westwicke.com