TELA Bio Announces 510(k) Clearance for OviTex® PRS Long-Term Resorbable for Plastic and Reconstructive Surgery

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Company continues design advancements of biologic-based materials for soft tissue repair and reinforcement

MALVERN, Pa., March 23, 2023 (GLOBE NEWSWIRE) -- TELA Bio, Inc. (NASDAQ: TELA), a commercial-stage medical technology company focused on providing innovative technologies that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy, today announced that the U.S. Food and Drug Administration has granted 510(k) clearance for the Company's OviTex PRS Long-Term Resorbable product. OviTex PRS Long-Term Resorbable is intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

OviTex PRS Long-Term Resorbable complements the Company's existing OviTex PRS portfolio, which includes OviTex PRS Permanent and OviTex PRS Short-Term Resorbable configurations. The OviTex PRS portfolio consists of products with two or three layers of high-quality tissue derived from ovine rumen, which is reinforced with either permanent or resorbable polymer for added strength, stabilization, and controlled stretch. These products are designed to improve outcomes by facilitating functional tissue remodeling while controlling the degree and direction of stretch. OviTex PRS Long-Term Resorbable enhances the OviTex PRS portfolio with specific design features including bi-directional stretch and a fully resorbable, long-term polymer for reinforcement.

“The OviTex PRS portfolio is integral to our mission to deliver next-generation soft-tissue repair solutions that offer clinical effectiveness and economic benefits,” said Antony Koblish, President and CEO of TELA Bio. “This new offering expands the clinical utility of the OviTex PRS portfolio and demonstrates our ability to leverage the tunable design of OviTex PRS to meet the varying needs of surgeons and patients in plastic and reconstructive surgery.”

To learn more, please visit www.ovitexprs.com.

About TELA Bio, Inc.
TELA Bio, Inc. (NASDAQ: TELA) is a commercial-stage medical technology company focused on providing innovative technologies that optimize clinical outcomes by prioritizing the preservation and restoration of the patient’s own anatomy. The Company is committed to providing surgeons with advanced, economically effective soft-tissue reconstruction solutions that leverage the patient’s natural healing response while minimizing long-term exposure to permanent synthetic materials. For more information, visit www.telabio.com.

About OviTex PRS
OviTex PRS Reinforced Tissue Matrix is intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

Do not use OviTex PRS in patients with a known sensitivity to materials of ovine (sheep) origin. For prescription use only. For additional important safety information, please see the OviTex PRS Instructions for Use.

Caution Regarding Forward-Looking Statements
This press release contains 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 differ materially and adversely from those indicated by such forward-looking statements including, among others the impact to our business from macroeconomic conditions, including the ongoing response to the COVID-19 pandemic, recessionary concerns, banking instability, and inflationary pressures, potentially impacting our ability to market our products, demand for our products due to the deferral of elective procedures, the labor and staffing environment in the healthcare industry, disruption in our supply chain, or pricing pressures concerning our products or the procedures using our products; our ability to achieve or sustain profitability; our ability to gain market acceptance for our products and to accurately forecast and meet customer demand; our ability to compete successfully; that data from earlier studies related to our products and interim data from ongoing studies may not be replicated in later studies or indicative of future data; that data obtained from clinical studies using our product may not be indicative of outcomes in other surgical settings; our ability to enhance our product offerings; development and manufacturing problems; capacity constraints or delays in production of our products; maintenance of coverage and adequate reimbursement for procedures using our products; product defects or failures. These and other risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in our filings with the Securities and Exchange Commission and available at www.sec.gov, including in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. 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 update 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.

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