TELA Bio Announces U.S. Commercial Launch of Robotic-Compatible OviTex® IHR – Addressing the Need for a More Natural Repair in Inguinal Hernia Procedures

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Targets the more than 665,000 inguinal hernia procedures performed annually in the United States (U.S.)

MALVERN, Pa., April 15, 2024 (GLOBE NEWSWIRE) -- TELA Bio, Inc. (NASDAQ: TELA), a commercial-stage medical technology company focused on providing innovative soft-tissue reconstruction solutions, today announced the U.S. launch of OviTex IHR (Inguinal Hernia Repair) Reinforced Tissue Matrix, specifically designed for use in laparoscopic and robotic-assisted inguinal hernia repair.

OviTex IHR is available in three configurations, consisting of a three- or four-layer anatomically shaped device or a three-layer rectangular device, to provide surgeons with a variety of options to address unique patient, technique or procedure-related characteristics. Each configuration has been designed for trocar-compatibility to enhance use of these products in laparoscopic and robotic procedures.

OviTex IHR builds on the existing OviTex portfolio, a next generation reinforced biologic that utilizes layers of ovine (sheep) rumen interwoven with just enough polymer suture for added strength, designed to minimize permanent polymer footprint. OviTex has over 8 years of clinical experience with more than 45,000 implantations and 35 published or presented works demonstrating its clinical efficacy in hernia repair, based on sales and internal data.

This data includes a prior retrospective study, *Minimizing Retained Foreign Body in Hernia Repair Using a Novel Technique: Reinforced Biologic Augmented Repair (ReBAR),* examining OviTex Core Permanent in a variety of hernia repair techniques and indications. The study, led by Dr. Paul Szotek, Medical Director of the Indiana Hernia Center, included the analysis of 259 patients who underwent robotic inguinal hernia TAPP repair using the ReBAR technique and demonstrated a low 1.2% recurrence rate with an average follow up of 1.5 years.

“Since 2018, utilization of OviTex in inguinal hernia repairs has consistently delivered exceptional clinical value, evidenced by low recurrence rates and an unprecedented level of patient satisfaction,” said Dr. Szotek. “The introduction of OviTex IHR signifies a pivotal moment in the advancement of the OviTex technology.”

“OviTex IHR, designed specifically for inguinal hernia repair and robotic-compatibility usage, is the next logical addition to our growing OviTex portfolio,” said Antony Koblish, President and Chief Executive Officer of TELA Bio. “The inguinal hernia market has historically been dominated by permanent synthetic mesh with few viable alternatives to address the shortcomings of those materials. With the introduction of OviTex IHR, we are addressing this need and providing surgeons with advanced, economically effective soft-tissue reconstruction solutions that leverage the patient’s natural healing response.”

To learn more, visit ovitex.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 IHR Devices
OviTex IHR is intended for use as a surgical mesh to reinforce and/or repair tissue where weakness exists. Indications for use include the repair of inguinal hernias that require the use of reinforcing material to obtain the desired surgical outcome.

Do not use OviTex IHR in patients with a known sensitivity to materials of ovine (sheep) origin. Use of OviTex IHR in this patient population may result in an allergic or immunological reaction.

The following adverse events have been reported for surgical repair of hernias (with or without a surgical mesh): pain, infection, dysphagia, hernia recurrence, dehiscence, abscess, adhesion, bowel obstruction, bleeding, fistula, seroma, perforation, mesh migration, and mesh contraction.

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, including with respect to the launch of OviTex IHR Reinforced Tissue Matrix. 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 impact of pandemics or epidemics, 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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