TELA Bio Announces U.S. Commercial Launch of LIQUIFIX™ – the Only FDA-Approved Liquid Adhesive for Internal Use in Hernia Surgery

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Strong and secure, LIQUIFIX is the first approved adhesive-based product to affix mesh without penetrating patient tissue

MALVERN, Pa., March 21, 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 LIQUIFIX FIX8™ Laparoscopic and LIQUIFIX Precision™ Open Hernia Mesh Fixation Devices. LIQUIFIX FIX8 is indicated for minimally invasive femoral and inguinal hernia repairs; and LIQUIFIX Precision is indicated for open femoral and inguinal hernia repairs. The LIQUIFIX devices are the only FDA-approved devices that affix mesh and approximate peritoneal tissue with liquid anchors. Based on market research, there are over 1.2 million hernia procedures performed each year in the United States (U.S.), the most common being inguinal hernia repair.

LIQUIFIX hernia mesh fixation devices eliminate the need for penetrating mechanical tacks, sutures, or staples by delivering a liquid adhesive that allows for precise and controlled mesh fixation. The products are designed to reduce risk of mechanical tissue trauma as they do not breach patient tissue, allowing surgeons to affix the mesh and minimize risks of complications. The LIQUIFIX products may offer greater utility for surgical mesh in inguinal hernia repair by enabling mesh fixation to sensitive areas, such as the “triangle of doom” and “triangle of pain” – regions containing sensitive arteries, veins, and nerves where traditional traumatic fixation methods could result in major vascular or nerve injuries leading to chronic pain.

“Aligned with our mission to prioritize the preservation and restoration of the patient’s own anatomy, this novel device is a natural addition to our fast-growing commercial portfolio,” said Antony Koblish, President and Chief Executive Officer of TELA Bio. “We’re excited to help surgeons across the U.S. advance the future of hernia repair fixation in robotic, laparoscopic, and open cases with this atraumatic approach.”

“Based on my experience, the device is easy to use and is safe and effective,” said Mr. Paul Wilson, Consultant General Surgeon, who has used LIQUIFIX in over 1500 laparoscopic hernia repairs in the United Kingdom (U.K.). “The fixation strength is very impressive. I have seen a significant benefit to the patient, with a major reduction in both acute post-op pain and chronic pain after surgery. This has been a game-changer for me.”

LIQUIFIX products are manufactured by U.K.-based Advanced Medical Solutions Limited (AMS), a world-leading specialist in tissue-healing technologies. AMS entered into an agreement with TELA Bio in 2023 to commercialize the LIQUIFIX products in the U.S., leveraging the company’s rapidly expanding hernia repair specialty salesforce and its focus on new technologies.

“Given the consistent strong performance of the LIQUIFIX products in Europe and other international markets over the past three years, we look forward to working with TELA Bio to grow adoption in the U.S.,” said Chris Meredith, Chief Executive Officer of AMS.

To learn more, visit liquifix.liquiband.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 LIQUIFIX™Devices

Indications for Use
The LIQUIFIX FIX8™ device is intended for use in laparoscopic surgical repair of groin (femoral and inguinal) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall and the approximation of the peritoneum.

The LIQUIFIX Precision™ Open Hernia Mesh Fixation device is intended for use in open surgical repair of groin (inguinal and femoral) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall.

Contraindications
The LIQUIFIX FIX8™ and LIQUIFIX Precision™ devices are not intended for use when prosthetic material fixation is contraindicated. Do not use or patients with a hypersensitivity to cyanoacrylate adhesives, formaldehyde or D&C Violet No. 2 dye. Do not use for the fixation of meshes constructed with polytetrafluoroethylene (PTFE) or materials other than polypropylene or polyester. Do not use the devices for closure or fixation of cerebral tissues, blood vessels or peripheral nerves.

Relevant Warnings
The use of LIQUIFIX is limited to those healthcare providers who are qualified to perform laparoscopic and open hernia repairs. A thorough understanding of the operating principles, risks versus benefits, and hazards involved in utilizing an endoscopic approach or surgical approach is necessary to avoid possible hazards to the user and/or patient. It is recommended that any healthcare provider who intends to use LIQUIFIX read the instructions for use in full, including directions, precautions, and warnings. Accidental bonding of unwanted tissue may occur due to misapplication of adhesive.

Potential Adverse Effects of the Device on Health
As with the majority of implanted devices, adverse reactions associated with the use of this device may include transient local irritation at the implant site and a transitory inflammatory foreign body response. Advanced Medical Solutions has determined the potential adverse effects (e.g. complications) listed below may be associated with the use of the LIQUIFIX device. These potential adverse events include, but are not limited to, the following:

- Toxic reaction

- Allergic reaction

Reference the LIQUIFIX FIX8™ Laparoscopic Hernia Mesh Fixation Device and LIQUIFIX Precision™ Open Hernia labeling for Additional Important Safety Information.

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 LIQUIFIX Non-Penetrating Fixation products. 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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