Amniox Medical Announces Presentation of Phase 2 Diabetic Foot Ulcer Trial Results at Symposium on Advanced Wound Care Spring Meeting

Results highlight safety, effectiveness of cryopreserved human umbilical cord (TTAX01) in managing complex, non-healing DFUs complicated by osteomyelitis

MIAMI (PRWEB) May 08, 2019 -- Amniox Medical, Inc., a TissueTech, Inc. company, announced today that the results of the Phase 2 pilot trial of its TTAX01 cryopreserved human umbilical cord for use in complex, non-healing diabetic foot ulcers (DFUs) will be featured as part of the oral abstract presentations during the Symposium on Advanced Wound Care (SAWC) Spring Meeting, May 7-11, 2019 in San Antonio, TX.

The trial, titled “A Multicenter, Open Label Phase 2 Pilot Trial of Subjects With Complex Non-healing Diabetic Foot Ulcers Treated With Standard Care Plus Cryopreserved Umbilical Cord Allograft (TTAX01),” started in October of 2017 and has since enrolled 32 participants. Results will be presented during Session K of the oral abstract presentations on Thursday, May 9:

Session Time: 2:55 pm
Session Name: K3.05 Phase 2 Trial of Human Umbilical Cord for Complex Non-healing Diabetic Foot Ulcers
Session Location: 008 A

“The interesting and impressive thing about the results being presented is the severity of wounds for the patients enrolled in this trial,” said William A. Marston, MD, Vascular Surgeon at University of North Carolina at Chapel Hill and lead investigator for the trial. “Typically, clinical trials of potential new therapies for diabetic foot ulcers rarely enroll patients whose wounds extend to muscle, fascia or bone, with clinical and radiographic evidence of underlying osteomyelitis. The goal of this clinical trial was specifically to look at those patients currently being underserved.”

The study was done in connection with TissueTech’s Investigational New Drug (IND) for a Biologics License Application (BLA) approval for this indication. TissueTech plans to initiate a Phase 3 trial in the near future.

Dr. Marston and study colleagues hypothesized that the application of the human placental umbilical cord tissue TTAX01 to the surface of a well-debrided complex diabetic foot ulcer will result in a higher proportion of wounds showing complete healing within 16 weeks of initiating therapy, with concomitant management of infection. Secondary outcomes included time to healing, rate of wound closure and other endpoints related to wound healing and complications.

“We are pleased to be able to present these results at SAWC Spring,” said Herbert B. Slade, M.D., Chief Medical Officer for TissueTech. “We look forward to showing the safety and effectiveness of the TTAX01 cryopreserved umbilical cord allograft as we work to address this serious unmet need for diabetic patients, which can often lead to amputation and significantly higher mortality rates under current care standards. With no currently cleared therapies for treatment, it is extremely important for us to look at advancements that can help these patients.”

Diabetes is a significant public health challenge and has become an increasingly substantial strain on the U.S. and other healthcare systems around the world. The Centers for Disease Control (CDC) estimates that more
than 30.3 million Americans, roughly 9.4% of the U.S. population, are affected by diabetes mellitus.1 More than 60% of non-traumatic amputations in the United States occur in people with diabetes, and a foot ulcer precedes 85% of lower-limb amputations in patients with diabetes.3 Contra-lateral leg amputation follows for 56% of patients within three to five years, and the five-year mortality rate for diabetic patients who have had a single-leg amputation is 60%.4 This figure is higher than the overall five-year mortality rate of breast cancer (10%), bladder cancer (19%), colorectal cancer (33%), and all cancers combined (32%).4

“We are extremely excited about the opportunity TTAX01 cryopreserved umbilical cord might bring to these patients in need,” said Frank Young, M.D., PhD, TissueTech Executive Vice President of Clinical and Regulatory Affairs. “Encouraging findings in this study will require confirmation in larger studies involving comparison to other treatment strategies for patients with complex, non-healing DFUs. We look forward to working with the FDA to plan the design of the Phase 3 clinical trial for TTAX01 in DFU with the goal of showing improved closure rates.”

In addition, Amniox will also host an industry-supported breakfast symposium, Orchestrating Regenerative Healing in Complex Wounds, on Wednesday, May 8th from 7:30–9am. Dr. Slade will provide a high-level overview of the Phase 2 Clinical Trial during the symposium, along with roundtable presentations and discussion from Javan Bass, D.P.M.; Alan Block, D.P.M.; Allen Raphael, D.P.M.; and Scheffer Tseng, M.D., Ph.D.. The goal of the symposium is to help educate physicians on regenerative wound healing, presenting the latest in clinical evidence that supports the healing of complex and chronic wounds in real-world situations.

SAWC Spring attendees will also be able to learn more about Amniox Medical products at booth #301 during exhibit hours Wednesday, May 8 – Friday, May 10.

About Amniox Medical, Inc.
Amniox Medical, Inc., a TissueTech, Inc. company, is a leader in the clinical application of amniotic membrane and umbilical cord-based products processed using TissueTech’s proprietary CryoTek© cryopreserved technology. Established in 2011, Amniox serves an unmet need for better surgical and therapeutic outcomes for chronic and complex wounds, orthopedics, sports medicine, spine, urology, gynecology, plastics, and general surgery.

About TissueTech, Inc.
TissueTech, Inc., the parent company of Amniox Medical, Inc. and BioTissue, Inc., pioneered the development and clinical application of amniotic tissue-based products. Amniox Medical develops and markets products for use in the musculoskeletal and wound care markets; BioTissue develops and markets products for the ophthalmology and optometry markets. Since the company’s inception, clinicians have performed more than 500,000 human implants of the company’s products and published more than 300 peer-reviewed studies supporting its technology platform. The Company’s first product, AmnioGraft®, is the only tissue graft designated by the FDA as homologous for promoting ophthalmic wound healing. Learn more at http://www.tissuetech.com.

References:
3. Alexiadou K and Doupis J. Management of diabetic foot ulcers. Diabetes therapy: research, treatment and
education of diabetes and related disorders. 2012; 3: 4-.

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