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Amniox Medical Announces Positive Results from Phase 2 Pilot Trial of TTAX01 Cryopreserved Human Umbilical Cord for Complex Non-healing Diabetic Foot Ulcers

Miami, Fla. – May 9, 2019 – Amniox Medical, Inc., a TissueTech, Inc. company and leader in the clinical application of amniotic membrane and umbilical cord-based products, announced today the results from its successfully completed Phase 2 pilot trial of TTAX01 cryopreserved human umbilical cord for use in complex, non-healing diabetic foot ulcers (DFUs) at the Symposium on Advanced Wound Care (SAWC) Spring Meeting in San Antonio, TX.

Herbert B. Slade, M.D., Chief Medical Officer for TissueTech, presented the trial results as part of the oral abstract presentations. The trial, titled Phase 2 Pilot Trial of Subjects With Complex Non-healing Diabetic Foot Ulcers Treated With Standard Care Plus Cryopreserved Umbilical Cord Allograft (TTAX01), included the primary outcome of complete wound healing over a 16-week period and secondary outcome measures of time to healing, rate of wound closure, healing in those with confirmed osteomyelitis, limb amputations required, and other ulcer-related complications.

Results showed that 50% of the Wagner 3 and 4 DFUs were healed within the 16-week trial period, followed by a one-month confirmation period, including 50% of DFUs with biopsy-confirmed osteomyelitis. On average, time to closure was 12.78 weeks. By the end of the study, an additional three patients had achieved initial closure and an additional two patients had a 99% reduction in the DFU area. Additional closures have been documented during an ongoing follow-up study with 83% of DFUs closed to-date. No major amputations were required during the study.

Conducted at 10 centers throughout the U.S., the trial enrolled a total of 32 patients with Wagner Grade 3 and 4 DFUs whose wounds extended to the muscle, fascia or bone, and with clinical and radiographic evidence of underlying osteomyelitis. DFUs ranged in size from 1.1 cm^2 – 32.8 cm^2 at baseline. All patients enrolled had DFUs that extended into the bone or joint with deep infections and loss of sensation.

William A. Marston, MD, lead investigator for the trial, noted the significance of such high healing rates for Wagner 3 and 4 DFUs, which currently have no FDA-cleared products indicated for their treatment.

“This is an underserved patient population that is at high risk for lower-limb amputations,” Dr. Marston added. “Five-year mortality rates are 60% once a diabetic patient undergoes leg

amputation, which is more than the 5-year mortality rate for all cancers combined. This is a true opportunity to provide an option that might help these patients."

Patients enrolled underwent an aggressive surgical debridement at the baseline visit, including biopsies of bone for histology and microbiologic testing at the start and completion of debridement in conjunction with systemic antibiotics. The TTAX01 cryopreserved human umbilical cord was secured to the debrided wound bed at baseline. For those wounds that did not show signs of healing, an additional application of TTAX01 was applied at 4-week intervals over the 16-week treatment period. For wounds that showed evidence of healing, additional applications of TTAX01 were withheld, based on observations from retrospective case series and learnings from the exploratory Amniox RENEW study. On average, 1.5 applications of TTAX01 cryopreserved human umbilical cord were applied for healing to occur.

"Our RENEW trial using NEOX provided us with a great deal of insight into how to best treat these patients," said Dr. Slade. "The primary objective of RENEW was safety, so we were maximizing exposure with treatment protocol allowing application on a weekly basis up to 10 times over a 12-week period. Although safety was determined through the study, the results also showed that greater frequency of application did not lead to improved efficacy, which helped us determine a more appropriate timeframe for additional applications for the Phase 2 study of the biologic TTAX01 in these more severe ulcers and re-application occurred only if the wound did not already show signs of healing."

Scheffer Tseng, MD, PhD, Chief Technology Officer and Co-founder of TissueTech, agreed.

"From the beginning, I set out to find ways to help the body have a more functional and natural healing process and to identify the biologic components of placental tissue that might help the body heal itself," Dr. Tseng said. "I believe these two studies are illustrative of this. In RENEW, we attempted to define a very aggressive treatment schedule, which disrupted the body's ability to utilize Amniox's cryopreserved umbilical cord products to help heal itself. The RENEW exploratory trial was a great experience for the team, as it allowed us to test a trial design with our commercial product that would inform us for the more rigorous design of this Phase 2 IND trial with our biologic form in a way that encouraged treatment no more than every four weeks and allowed the physician to withhold additional treatment if they saw positive signs of healing."

This trial was done in connection with TissueTech's Investigational New Drug (IND) for a Biologics License Application (BLA) approval for this indication. TissueTech will now be working with the FDA to determine the next steps for moving to a Phase 3 clinical study with TTAX01 for DFUs with the ultimate goal of achieving Biologics License Application Approval for the product.

"We are proud of the investments we have made to become a biologics provider and hope to gain biologic license approval for newly formulated versions of our HCT/P products over the coming years," said Amy Tseng, CEO and Co-founder of TissueTech. "This study demonstrates a small portion of the unmet need that our products might be able to fill for DFU patients and reinforces our status as the leader in the scientific understanding and innovative application of placental tissue for regenerative healing."

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. Connect with Amniox on our Website, Facebook, LinkedIn and Twitter.

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. The 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 www.tissuetech.com.

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