TissueTech Highlights Clinical Experience Showing In-Utero Spina Bifida Repair with NEOX® Wound Allograft

MIAMI – July 26, 2016—TissueTech Inc., announced the publication of initial clinical experience with in-utero spina bifida repair using NEOX cryopreserved umbilical cord allograft marketed by Amniox Medical Inc., a TissueTech company. The data were published in Obstetrics & Gynecology by Dr. Ramesha Papanna of UTHealth McGovern Medical School and the Fetal Center at Children’s Memorial Hermann Hospital, Houston, Texas.

Spina bifida is characterized by the incomplete development of the coverings of the brain, spinal cord or meninges – the protective covering around the brain or spinal cord – according to the National Institute of Neurological Disorders and Stroke. It is the most common neural tube defect in the country, affecting 1,500 to 2,000 of the more than 4 million babies born each year. The defect can result in paralysis, urinary or bowel dysfunction and mental retardation.

The paper highlights two pregnancies where the fetuses were found to have large myeloschisis defects and underwent in-utero spina bifida repair at mid-gestation with closure of the skin defect using NEOX CORD 1K® Wound Allograft.

Following the procedures, both pregnancies were uncomplicated and deliveries occurred at 37 weeks by planned Cesarean. The repair sites were intact with no evidence of cerebrospinal fluid leakage and with skin regenerated after delivery over a period of three to four weeks. Short-term outcomes after delivery showed reversal of hindbrain herniation, minimal spinal cord tethering, and normal function of the lower extremities, suggesting that cryopreserved human umbilical cord tissue for in-utero spina bifida repair may be a suitable patch option for the spina bifida closure.

“The results of these two cases suggest the application of an umbilical cord patch is a viable way to treat spina bifida in-utero,” said Dr. Papanna. “Cryopreserved human umbilical cord is currently widely used for ocular surface repair and chronic skin ulcers because its innate regenerative properties facilitate faster healing with minimal scarring. The findings from this study suggest these unique properties may eliminate the scar formation associated with traditional repair methods and reduce the need for future surgeries to address that complication.”

“Dr. Papanna’s experience adds to the considerable body of clinical experience and evidence supporting TissueTech’s proprietary technology,” said Amy Tseng, Chief Executive Officer of TissueTech, “Doctors continue to lead the innovation driving our discovery of the full healing potential of cryopreserved umbilical cord tissue.”

“These cases provide additional evidence of the regenerative properties of CryoTek® preserved umbilical cord tissue,” said Dr. Scheffer Tseng, Chief Science Officer and Co-Founder of TissueTech. “TissueTech was the first to develop this technology for clinicians and continues to lead the field in developing new and innovative applications that benefit patients in the most need.”
In utero, wound healing occurs rapidly and with minimal scar. This restorative ability is innate to placental tissues and can be preserved and transplanted to other wound environments. Heavy chain hyaluronic acid/pentraxin-3 (HC-HA/PTX3) is the key protein complex present in these tissues to orchestrate that regenerative healing process. TissueTech is the first provider of a human tissue allograft composed of both umbilical cord and amniotic membrane. The Company utilizes its proprietary CryoTek process, a cryopreservation technology, to preserve the biological and structural integrity of these tissues more effectively than other available technologies.

**About TissueTech, Inc.**

TissueTech, Inc., the parent company of Amniox Medical and BioTissue, Inc., pioneered the development and clinical application of regenerative, 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 National Institutes of Health (NIH) has supported TissueTech's research with more than 25 continuous years of research grants. Since the company's inception, clinicians have performed more than 200,000 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 while suppressing scarring and inflammation.

**About Amniox Medical, Inc.**

Founded in 2011 to serve the orthopedic and wound care markets, Amniox Medical Inc. is dedicated to developing and marketing regenerative therapies processed from umbilical cord and amniotic membrane utilizing its proprietary CryoTek technology. This process has been proven to preserve the innate biological and structural properties of the matrix, which can then be transplanted to adult wound and surgical environments. Amniox Medical procures its tissue through elective donation following healthy live birth via Cesarean section. Thorough donor screening is performed to ensure safety of its products. For additional information, please visit [http://www.amnioxmedical.com](http://www.amnioxmedical.com).

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