Study Demonstrating Improved Outcomes in Pain Reduction and Function for Discectomy Patients with CLARIX® 100 Highlighted in Medical Journal

Proprietary technology demonstrates significant improvement in short-term and long-term outcomes

ATLANTA – July 10, 2017 – AMNIOX Medical, Inc., a TissueTech™, Inc. company, announced today that the results of a clinical study on the efficacy of CLARIX Cryopreserved Amniotic Membrane in lumbar microdiscectomy surgery was published in the May 2017 online issue of Clinical Spine Surgery.

The research was led by D. Greg Anderson, MD, of the Rothman Institute in Philadelphia. The published results include 80 patients who were prospectively randomized; 40 patients received the CLARIX 100, a CryoTekÒ cryopreserved placental tissue, placed in the annular defect upon removal of the disc fragment during microdiscectomy, and another 40 received standard care, the exact same surgery without adjunctive tissue placement. Patients who received CLARIX 100 demonstrated greater improvement in both pain reduction and in daily function as early as six weeks post-surgery, with consistent continued improvement throughout the study follow-up endpoint of two years.

None of the patients who received CLARIX 100 experienced re-herniation during the two-year follow-up period, while 7.5 percent of the control group demonstrated re-herniation. Specifically, three control group patients experienced a re-herniation at the same level, with two of the three requiring spinal fusion to manage persistent pain.

A third cohort of 40 patients – not included in the results published in Clinical Spine Surgery – is currently being enrolled. Those patients are receiving CLARIX CORD 1K®, the first cryopreserved umbilical cord tissue available to the market. This umbilical cord product is more potent than the amniotic membrane product. Dr. Anderson presented the interim findings of the umbilical cord cohort at the International Society for the Advancement of Spine Surgery 2017 conference in April; and those early results indicate that patients are responding even more favorably to treatment with the proprietary umbilical cord technology.

“The data drawn from this study exhibits a significant improvement in clinical outcomes for patients receiving placental tissue following lumbar microdiscectomy, as measured by ODI and SF-12 PCS for pain and function respectively,” Dr. Anderson said. “Additionally, there was a lower rate of recurrent herniation with the use of a placental tissue graft compared to the outcomes associated with microdiscectomy procedures without these tissues. These results indicate the application of these tissue grafts significantly reduced pain, enhanced the healing response and improved post-surgical outcomes.”

“This study adds to increasing clinical evidence concerning amniotic and umbilical cord tissue for reducing pain and improving function following surgical procedures,” said Tom Dugan, Chief Executive Officer of Amniox Medical. “This is another important example of the expanding role for amniotic and umbilical cord tissue as regenerative therapies to improve surgical outcomes.”

Amniox Medical’s parent company, TissueTech, pioneered the commercialization and clinical application of human umbilical cord and amniotic membrane to promote regenerative healing. This restorative ability is innate to these placental tissues and can be preserved and transplanted to adults. Heavy chain hyaluronic acid...
Acid/pentraxin-3 (HC-HA/PTX3) is the key protein complex present in these tissues to orchestrate that regenerative healing process. Amniox Medical utilizes its proprietary CryoTek process, a cryopreservation technology, to preserve the biological and structural integrity of these tissues more effectively than other available technologies. Since the company’s inception, clinicians have performed more than 300,000 human transplants of its products and published more than 300 peer-reviewed studies supporting its technology platform.

**About Amniox Medical, Inc.**

Founded in 2011 to serve the orthopedic and wound care markets, Amniox Medical 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).

**About TissueTech, Inc.**

TissueTech, Inc., the parent company of Amniox Medical, Inc. and BioTissue®, Inc., pioneered the advancement 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 300,000 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 opthalmic wound healing while suppressing scarring and inflammation.