AMNIOX Highlights Studies Finding CLARIX® FLO and CLARIX® CORD 1K Improving Foot and Ankle Outcomes

Umbilical Cord Allograft Improves Outcomes in Plantar Fasciitis Treatment and Tarsal Coalition Repair

ATLANTA, GA – July 25, 2016 — AMNIOX Medical, Inc., a TissueTech, Inc. company, highlighted the results of two studies presented at the American Orthopaedic Foot & Ankle Society (AOFAS) Annual Meeting. Dr. David Garras of Midwest Orthopaedic Consultants, an assistant professor at the University of Illinois at Chicago, and Dr. Ryan Scott, of the CORE Institute in Phoenix, presented Plantar Fasciitis Treatment with Particulate Human Amniotic Membrane. Dr. Donald Covell, Dr. Bruce Cohen, Dr. Kent Ellington, Dr. Carroll Jones, Dr. Hodges Davis and Dr. Robert Anderson, all from OrthoCarolina Foot and Ankle Institute in Charlotte, North Carolina, presented The Use of Cryo-Preserved Umbilical Cord Plus Amniotic Membrane Tissue in the Resection of Tarsal Coalition.

Dr. Garras’ findings concerned 60 patients treated with ultrasound-guided injections of CLARIX FLO particulate umbilical cord and amniotic membrane. An interim review of patients who had completed the full 18-week follow-up period demonstrated that all treatments showed statistically significant reduction of foot pain as well as an increase in Foot Ankle Ability Movement for both daily living and sport subscales. Dr. Garras concluded CLARIX FLO significantly decreased pain from baseline and improved overall functional recovery.

Plantar fasciitis is the most common cause of heel pain affecting 1 million patients annually. Conservative therapies are ineffective in 10 to 15 percent of patients. Other available treatments including corticosteroids and surgery can carry risks such as plantar fascia rupture, biomechanical instability and post-operative pain.

“The early results of this study are very promising with the significant improvement in pain and function being demonstrated by these patients,” said Dr. Garras. “For the large number of patients that fail conservative therapies, this is a minimally invasive treatment option with no apparent short or long-term side effects.”

Dr. Covell presented a retrospective review of 14 patients who received the CLARIX CORD 1K matrix as an interpositional graft during tarsal coalition surgery. His findings included a median 89.5% improvement in pain with improved range of motion and no infection or wound complications. Dr. Covell concluded CLARIX CORD 1K is a viable option for treatment of tarsal coalition.

A tarsal coalition is an abnormal connection of two or more bones in the foot. The bones affected are located toward the back of the foot and in the heel, and the connection of the bones can result in a severe, rigid flatfoot. Although tarsal coalition is often present at birth, signs of the disorder typically surface during early adolescence when the foot may become stiff and painful, and everyday physical activities are often difficult.
“Since incorporating the umbilical cord allograft as an adjunct to many of our foot and ankle procedures we have observed dramatically improved outcomes in a number of indications,” stated Dr. Bruce Cohen. “This is just the first of several clinical studies that will show the significant clinical benefits that patients experience due to this unique technology.”

“Clinical evidence regarding umbilical cord tissue in regenerative healing is continuing to accumulate,” said Tom Dugan, Chief Executive Officer of Amniox Medical. “CLARIX CORD 1K and CLARIX FLO are important options for physicians and the practical applications are clear in this data.”

CLARIX FLO is the particulate form of CLARIX 100 and CORD 1K™ Regenerative Matrix. It is comprised of the Umbilical Cord and Amniotic Membrane which are rich in collagen, fibronectin, hyaluronic acid, growth factors and particularly heavy chain hyaluronic acid (HC-HA). CLARIX FLO is the only available injectable product to employ the benefits of umbilical cord, providing higher volumes of the critical matrix proteins innate to the tissue. CLARIX CORD 1K is the first umbilical cord allograft commercially available for clinical transplantation.

In utero, wound healing occurs rapidly and with minimal scar. This restorative ability is innate to placental tissues, including umbilical cord and amniotic membrane. Heavy chain hyaluronic acid/penetratin-3 is the key protein complex present in these tissues to orchestrate the healing process. Amniox Medical is the first provider of a human tissue allograft composed of both umbilical cord and amniotic membrane. Amniox utilizes its proprietary CryoTek™ process, a cryopreservation technology, to preserve the biological and structural integrity of the native tissue and published studies have demonstrated that the CryoTek process more effectively preserves the structural and biological integrity of the tissue.

**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 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) have 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.

###