PRESS RELEASE

Contact:

Jon Werner
Director of Marketing
(410) 715-1700

ACell Initiates Post-Market Study of MatriStem® Pelvic Floor Matrix

Columbia, MD - (July 9, 2014) – ACell, Inc., a leading regenerative medicine company focused on the development, manufacturing and commercialization of tissue repair products, today announced enrollment of the first patient in a U.S. Phase IV clinical trial (NCT02021279; www.clinicaltrials.gov) evaluating the safety and long-term effectiveness of ACell’s MatriStem® Pelvic Floor Matrix device as compared to native tissue repair for the treatment of pelvic organ prolapse. The prospective, non-randomized trial will measure post-operative pelvic pain, quality of life and long-term need for retreatment.

More than 300,000 cases of pelvic organ prolapse are treated surgically in the United States each year, and it is estimated that 20% of women will undergo some form of pelvic surgery in their lifetime.

The study is part of ACell’s commitment to conducting postmarket surveillance for MatriStem Pelvic Floor Matrix in response to the 522 Order issued to all manufacturers of transvaginal pelvic meshes by the United States Food and Drug Administration (FDA) in January 2012. Collaborations between the American Urogynecologic Society (AUGS) and other industry sponsors led to the development and implementation of the American Urogynecologic Society’s Pelvic Floor Disorders Registry.

The multi-center, prospective, non-randomized trial will enroll 162 subjects at qualified sites across the United States. “ACell is proud to be partnering with an impressive group of surgeons to demonstrate the safety and effectiveness of MatriStem devices in pelvic floor repair. We remain committed to this product category and to meeting the growing demand for devices that promote constructive remodeling,” said Jim DeFrancesco, CEO.

The first patient was enrolled at Princeton Urogynecology under Heather van Raalte, M.D., a fellowship trained and board certified urogynecologist specializing in the treatment of female pelvic floor disorders.

“Pelvic organ prolapse is a significant quality of life issue for hundreds of thousands of women. This study will contribute to a better understanding of how physicians can help these patients achieve positive outcomes,” said Dr. van Raalte.
The objective of the trial is to show that treatment with MatriStem Pelvic Floor Matrix is at least as safe and effective as treatment with native tissue repair, as assessed through anatomic and subjective assessments over a 36-month follow up period.

MatriStem devices have received multiple 510(k) clearances from the FDA. MatriStem Pelvic Floor Matrix is specifically intended for implantation to reinforce soft tissue where weakness exists in gynecological anatomy including vaginal prolapse repair, reconstruction of the pelvic floor and pubourethral support.

ACell offers the next generation of regenerative medicine through the development and commercialization of unique extracellular matrix products to repair and remodel damaged tissues in a broad range of applications. Its patented MatriStem ECM medical devices facilitate constructive remodeling by the body, and are available in particle and sheet forms for the management and reinforcement of wounds and various surgical procedures. For more information, visit www.acell.com.

About ACell, Inc.
ACell, Inc. is a leading company in the field of regenerative medicine, focused on the development, manufacturing and commercialization of tissue repair products. Its medical devices are cleared for a variety of indications and are marketed under the brand name “MatriStem.” A privately held company, ACell produces MatriStem at its full scale manufacturing facility in Lafayette, IN, and markets its products to physicians in the U.S. through a national direct sales force. For more information, call (800) 826-2926 or visit www.acell.com.

About MatriStem®
MatriStem products are porcine-derived extracellular matrix (ECM) scaffolds that contain the epithelial basement membrane from porcine urinary bladder tissue, or urinary bladder matrix (UBM). UBM is a layer of tissue that facilitates a constructive tissue remodeling response by the patient’s body. It provides MatriStem products with several distinguishable characteristics, including the ability to be resorbed by the patient as it is replaced by site appropriate tissue following implantation; the ability to be used “off-the-shelf” and stored at room temperature, with up to a two year shelf life; and superior ease-of-use characteristics. MatriStem products are indicated for use in a wide range of tissue repair applications and come in a range of sizes and thicknesses. They have been cleared for use in general surgery, gynecological surgery and a wide range of wounds, including diabetic foot ulcers (DFU), venous leg ulcers (VLU), pressure, surgical, and tunneled wounds. Refer to the IFU supplied with each device for indications, contraindications and precautions. All MatriStem devices are made in the USA.

###