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## **Tengion Launches Second Phase 2 Clinical Trial of Regenerated Human Organ *Trial Aims to Study Safety and Efficacy of Tengion's Neo-Bladder Construct in Spinal Cord Injury Patients***

East Norriton, PA (September 17, 2007) – Tengion, Inc., a leader in regenerative medicine, announced today it has initiated a Phase 2 multi-center clinical trial of its neo-bladder construct, derived from a patient's own cells. The U.S.-based study is being conducted in 10 adult patients with neurogenic bladder due to spinal cord injuries. Neurogenic bladder is a condition that can occur due to spinal cord injury and may lead to kidney failure and incontinence, even when patients receive optimal medical treatment.

This Phase 2 trial initiation follows the successful completion of enrollment in the company's first (Phase 2) clinical trial of the autologous neo-bladder construct in pediatric patients with neurogenic bladder due to spina bifida. The commencement of Tengion's spina bifida Phase 2 clinical trial was announced in the first quarter of 2007.

"Tengion's novel regenerative medicine platform aims to address the significant limitations of current treatment options for patients with organ and tissue failure or loss," said Steven Nichtberger, M.D., President and CEO of Tengion. "Our neo-bladder constructs, which harness the body's natural ability to regenerate organs and tissues using a patient's own cells, hold the promise to meet critically important unmet medical needs. We look forward to announcing results from both of these Phase 2 clinical studies."

Similar to the Phase 2 study in pediatric patients, the new Phase 2 study in adult patients with spinal cord injuries is evaluating the safety and effectiveness of the neo-bladder construct at one year after implantation. The neo-bladder construct design is based on nearly two decades of research from Children's Hospital Boston (a teaching affiliate of Harvard Medical School), MIT, The Wake Forest Institute for Regenerative Medicine and Tengion. Previous academic clinical research and results of use of the neo-bladder at Children's Hospital Boston were described in an article published in *The Lancet* on April 15, 2006.

The neo-bladder constructs for patients in both Phase 2 clinical trials are being developed at Tengion's state-of-the-art manufacturing facility using cells taken from a small biopsy of each patient's bladder. Each neo-bladder construct consists of a biodegradable scaffold seeded with cells cultured by Tengion scientists from the patient's own (*i.e.*, autologous) healthy cells. A surgeon implants the neo-bladder construct in the patient's body, where it is designed to harness the body's inherent regenerative capabilities resulting in a regenerated bladder with improved functionality. The primary efficacy endpoint of the trial is urodynamic function of the neo-bladder at one year post-implantation. Data on the safety profile of the product will continue to be collected after the one-year endpoint measurement date. The trial is expected to complete enrollment over the next few months.

If the implanted neo-bladder constructs prove safe and effective, they have the potential to reduce the risks and complications associated with present means of treating failing bladders in adults with spinal cord injuries. The most common surgical procedure currently used to treat patients with failing bladders is known as enterocystoplasty, a procedure that was developed more than 100 years ago that uses the patient's own bowel tissue to augment the failing bladder. This procedure is associated with substantial and well-described side effects and risks.

"Bladder failure patients have not seen new treatment options in decades, and Tengion's technology has the potential to be a compelling advance," said Roger R. Dmochowski, M.D., professor with Vanderbilt University's Department of Urology. "We have been encouraged by results to date and look forward to the continued evaluation of the neo-bladder constructs."

### **Tengion Technology Platform**

Employing breakthroughs in regenerative medicine, Tengion seeks to augment or replace diseased or defective tissues or organs. The Company's patented technology platform utilizes regenerative medicine and tissue engineering approaches. Tengion is the first company to demonstrate an ability to identify and expand progenitor (healthy) cells across a variety of tissues and organs and to unlock these cells' potential to harness the body's regenerative powers. The progenitor cells, which come from the patient, while not yet fully differentiated, are biologically committed to becoming a certain cell type (like a bladder cell), and they retain their ability to regenerate.

### **About Spinal Cord Injury**

According to the National Spinal Cord Injury Association, approximately 250,000 – 400,000 individuals in the United States have spinal cord injuries. Every year, approximately 11,000 people sustain new spinal cord injuries – equating to approximately 30 new injuries every day – with most of these injuries occurring as a result of auto and sports accidents, falls, and industrial mishaps. An estimated 60 percent of these individuals are 30 years old or younger, and the majority of them are men.

### **About Tengion**

Founded in 2003, Tengion is a leader in developing autologous neo-organs and tissues, such as bladders, that are derived from the patient's own (autologous) cells. Tengion's proprietary approach to regenerative medicine has the potential to enable people with organ and tissue failure to lead healthier lives without donor transplants or the side effects of current therapies. The products being developed by Tengion are solely focused on important unmet clinical needs where the company's technology can offer a unique and compelling medical advance. For more information, visit [www.tengion.com](http://www.tengion.com).

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