

# Press Statement



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## **TENGIION LAUNCHES FIRST PHASE II CLINICAL TRIAL OF REGENERATED HUMAN ORGAN**

*Trial Aims to Study Safety and Efficacy of Urinary Neo-bladder Construct*

East Norriton, PA (January 5, 2007) - Tengion, Inc., announced today it has initiated a Phase II multi-center clinical study for its urinary neo-bladder construct. The study is being conducted in pediatric patients with spina bifida who have failing bladders that predispose them to a risk of kidney failure and incontinence even when they receive optimal medical therapy.

The study is evaluating the safety and effectiveness of the neo-bladder construct, whose design is based on nearly two decades of research from the Harvard Medical School's Children's Hospital Boston, MIT, and Tengion. A previous academic clinical experience from the Children's Hospital was described in an article published in *The Lancet* on April 3, 2006.

The neo-bladder constructs for the patients in this study are being developed at the Tengion pilot manufacturing facility using healthy cells taken from a small biopsy of each patient's failing bladder. Each construct consists of a biodegradable scaffold seeded with urothelial and smooth muscle cells cultured by Tengion scientists from the patient's own (i.e., autologous) healthy cells. The neo-bladder construct is surgically implanted in the patient's body, where it is designed to harness the body's inherent regenerative capabilities resulting in an improved bladder that integrates with the patient's body as the scaffold degrades.

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 children with spina bifida. The most common procedure currently used is known as augmentation enterocystoplasty. This procedure, first developed over 100 years ago, uses the patient's own bowel tissue to augment the failing bladder. This treatment is associated with substantial and well described side effects and risks.

"The successful IND filing and timely start of this first FDA allowed Phase II clinical trial represents an important milestone for Tengion as we advance towards our goal of delivering potentially transformational treatment options to patients with neurogenic bladders. Encouraged by our preclinical experience and published academic clinical experience, we are enthusiastic about the potential of our novel integrated technology platform. We look forward to the results of this important trial," said Steven Nichtberger, M.D., President and CEO of Tengion. (Neurogenic bladder is a term applied to a malfunctioning urinary bladder due to neurological dysfunction caused by disease or injury.)

"The current treatment options for patients with bladder failure have been unchanged for decades," said David Joseph, M.D., University of Alabama-Birmingham, one of the Principal Investigators of this clinical trial. "This Tengion-sponsored trial represents a new approach that, if successful, could represent an exciting alternative to augmentation enterocystoplasty."



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### **Study Design**

The open-label, non-comparative Phase II study is enrolling 10 pediatric patients with neurogenic bladder secondary to spina bifida, who are candidates for augmentation enterocystoplasty based on inadequate response to medical management. Using cells obtained by a surgeon who takes a bladder biopsy from each patient, Tengion isolates and expands the autologous urothelial and smooth muscle cells in its pilot manufacturing facility and seeds a biodegradable scaffold to create a neo-bladder construct that is individualized for each patient. The neo-bladder construct is then surgically implanted by the patient's own physician onto the patient's failing bladder and serve as a template for the regeneration of a functioning bladder following implantation.

### **Tengion Technology**

Tengion's patented technology integrates multiple breakthroughs in tissue engineering and regenerative medicine. While it has long been held that the body contains cells with regenerative power, Tengion's technology identifies these healthy cells and has the potential to unlock their ability to create a variety of tissues and organs on a commercial scale. These autologous progenitor cells, which come from the patient, are genetically committed to becoming a specific cell type (e.g., a bladder cell), but they are not yet fully differentiated. The cells have the potential to divide and organize to become functional tissue or organ.

### **About Spina Bifida**

Spina bifida is a neural tube defect that happens in the first month of pregnancy when the spinal column does not close completely. According to the Mayo Clinic, approximately one in every 2,000 children born in the U.S. is diagnosed with spina bifida. Risk factors include the presence of a neural tube defect in a previous child, lack of folic acid, some medications, diabetes and the mother's age. Most patients with spina bifida have neurogenic bladders. Neurogenic bladders function poorly and over time, without correction, can result in kidney damage and ultimately kidney failure.

### **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. For more information, visit [www.tengion.com](http://www.tengion.com).

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