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# TissueGene Initiates Patient Enrollment for a Phase II Study of TG-C for Osteoarthritis of the Knee

ROCKVILLE, Md., May 19, 2011 /PRNewswire/ -- TissueGene, Inc. announced today that it has initiated patient enrollment for a U.S. Phase II clinical trial of its lead product candidate TG-C. TG-C involves human allogeneic chondrocytes developed to produce the therapeutic protein TGF-beta1 for the regeneration of cartilage in patients suffering from severe osteoarthritis of the knee.

The randomized, double-blind, placebo-controlled Phase II study will evaluate the safety and efficacy of TG-C in patients with chronic degenerative joint disease (DJD) of the knee.

Patients will receive an intra-articular injection of either TG-C or placebo to the damaged joint area with primary and secondary endpoints involving evidence of symptomatic improvement and cartilage regeneration, respectively. This multi-center study will be conducted at hospitals and clinical research centers across the United States specializing in orthopedic research and is expected to include 100 patients. In conjunction with these efforts, TissueGene's licensing partner, Kolon Life Science, Inc. (KOSDAQ: 102940) anticipates the initiation of a Phase IIb single-dose study for TG-C in Korea by 3Q 2011, having previously received regulatory allowance by the Korean FDA to proceed.

"We are pleased to have reached another significant milestone with the start of our U.S. Phase II study of TG-C," stated Dr. Kwan Hee Lee, Chief Medical Officer of TissueGene.

"We believe that TG-C has the potential to become the first noninvasive treatment for osteoarthritis by regenerating cartilage through a simple injection into the knee."

## **About TissueGene, Inc.**

TissueGene, Inc. is a Maryland-based biopharmaceutical company with a pipeline of noninvasive regenerative medicine therapies in the field of cell therapy. TissueGene's core technology employs a form of cell-mediated therapy to deliver therapeutic proteins to localized areas of damaged tissue. The company is currently developing four product candidates for the regeneration of cartilage (TG-C), bone (TG-B), disc (TG-D), and nerve tissue (TG-N) for the treatment of various orthopedic diseases. For more information, please visit <http://www.TissueGene.com>.

## **About Kolon Life Science, Inc.**

Kolon Life Science, Inc. (KOSDAQ: 102940), a subsidiary company of Kolon Group, is a leading Korean-based biochemical company focused on pharmaceutical ingredients and environmental biochemicals. Its pharmaceutical business division provides active pharmaceutical ingredients and pharmaceutical intermediates ranging from zaltoprofen and flurbiprofen to argatroban and voglibose. For more information, please visit <http://www.kolonls.co.kr>.

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