



TissueGene Announces Regulatory Allowance to Initiate Phase IIa Study of TG-C in South Korea for Osteoarthritis of the Knee

ROCKVILLE, MD., March 03, 2009 – TissueGene, Inc. announced that its South Korean licensing partner Kolon Life Science, Inc. (KLS) has received regulatory allowance from the Korea Food and Drug Administration (KFDA) to initiate a Phase IIa clinical trial of TissueGene-C (TG-C) in patients with severe osteoarthritis of the knee. TG-C has been developed for the localized delivery of allogeneic human cells expressing TGF-beta1 in order to induce the regeneration of cartilage.

In Asia, TissueGene has licensed intellectual property rights to KLS, a subsidiary of Kolon, for the clinical development and commercialization of TissueGene's lead product candidates TG-C and TG-B, developed for the regeneration of cartilage and bone, respectively. Under the terms of the agreement, TissueGene has received an undisclosed up-front payment and will receive on-going royalty payments based upon future sales. TissueGene is currently completing Phase I clinical trials in the U.S. and continues to work closely with KLS in order to coordinate their regulatory efforts and efficiently conduct parallel clinical trials for TG-C in both the U.S. and Korea.

The Phase IIa clinical trial is designed as a randomized, multi-center study in order to evaluate the safety and efficacy of TG-C in patients with Grade IV Degenerative Joint Disease (DJD) of the knee, who have been unresponsive to existing therapies. The patients will receive an intra-articular injection to the damaged joint area at one of two dose levels of TG-C. The primary endpoint of the trial will be evidence of symptomatic improvement and the secondary endpoint will be evidence of cartilage regeneration through MRI evaluation.

"The launch of this Phase II study represents a critical step in the development of a commercially and clinically viable mechanism to initiate regeneration of cartilage for patients suffering from osteoarthritis," stated Dr. Kwan Hee Lee, President and CEO of TissueGene. "And I believe our success thus far can be attributed primarily to the strategic alliance between TissueGene, Kolon and KLS. By bridging our domestic and international resources, this business model has not only enabled for rapid preclinical and clinical development, but has allowed for innovative cost control mechanisms and significant long-term growth opportunities."

About TissueGene, Inc.

TissueGene, Inc. is a Maryland-based biopharmaceutical company with a strong global vision focused on developing a proprietary and innovative suite of regenerative orthopedic therapeutic products. Founded in 1999, the Company's primary pipeline is focused on the treatment and regeneration of damaged cartilage, bones, disc and nerves. The Company's core technology employs a form of cell-mediated gene therapy to deliver well-known therapeutic proteins to localized areas of damaged tissue. The sustained expression of such proteins, along with the cellular matrix it is delivered in, initiates rapid and permanent repair of injured tissue without the need for invasive surgical procedures. The Company has successfully demonstrated the growth of cartilage, bone, nerve and tendons in animals. For more information, please visit www.TissueGene.com.

