November 17, 2014

KOLON TISSUEGENE

TissueGene Receives Recommendations from FDA on Pathway to Phase 3 Trial of TG-C for Treatment of Osteoarthritis of the Knee

ROCKVILLE, Md., Nov. 17, 2014 /PRNewswire/ -- TissueGene, Inc., a clinical stage biopharmaceutical company, has received recommendations from the U.S. Food and Drug Administration ("FDA") to submit its Phase 3 protocol for review under the Special Protocol Assessment ("SPA"). These recommendations were in response to TissueGene's request for an end-of-Phase 2 meeting to discuss plans for pivotal Phase 3 randomized controlled trials ("RCT") of TG-C for treatment of osteoarthritis of the knee.

Woosok Lee, the President and CEO of TissueGene said, "Following our meeting with the FDA this week, we believe that a significant milestone has been achieved in moving forward to Phase 3 trials for treating osteoarthritis of the knee, a debilitating disease with a significant unmet need. Our goal is to work collaboratively with the FDA on their recommendations to complete the SPA review of our protocol."

About TissueGene, Inc.

TissueGene, based in Rockville, Maryland, specializes in regenerative therapies affecting the joints, nerve and bone. Its novel osteoarthritis drug, TG-C, is designed to conveniently and effectively treat osteoarthritis of the knee by reducing pain, increasing function and slowing the progression of the disease without the side effects usually seen with other palliative options such as NSAIDs or steroids. TissueGene has completed Phase 2 trials of TG-C for an allogeneic cell therapy for osteoarthritis of the knee. Information can be found at the NIH registry, www.clinicaltrials.gov. For additional information about TissueGene, Inc., please visit the Company's website at www.TissueGene.com.

Logo - https://photos.prnewswire.com/prnh/20141107/157412LOGO

SOURCE TissueGene, Inc.