TissueGene, Inc. Announces Special Protocol Assessment (SPA) Agreement with the Food and Drug Administration (FDA) for its Phase 3 Clinical Trial of Invossa™ for Patients Suffering from Osteoarthritis of the Knee

ROCKVILLE, MARYLAND, May 15, 2015 -- TissueGene, Inc. announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design, endpoints and statistical analysis plan for a Phase 3 clinical trial for Invossa™, an allogeneic cell therapy for osteoarthritis of the knee. There are an estimated 9 million Americans suffering from osteoarthritis of the knee, one of the leading causes of disability in the United States.

As noted by the FDA in its May 15, 2015 letter to TissueGene, "[W]e have determined that the design and planned analyses of your study sufficiently address the study objectives and this study is adequately designed to provide the necessary data that, depending upon outcome, could support a license application submission for drug approval."

This double-blinded randomized controlled trial will enroll approximately 1,020 patients with osteoarthritis of the knee. Patients will receive an injection of either Invossa™ or a placebo. The trial is designed to evaluate improvement in knee function and pain and perhaps most importantly, disease modification as measured by joint space width. As per the SPA, the Company plans to use data from the trial as the basis for submission of a Biologics License Application (BLA) for Invossa™. Subject to BLA approval, Invossa™ would be the first disease modifying osteoarthritis drug (DMOAD) marketed for the treatment of osteoarthritis of the knee.

Mr. Woosok Lee, President and CEO, commented, "The SPA agreement is a major milestone for us as it represents the first clearly defined development and regulatory pathway for the approval of Invossa™ for the treatment of osteoarthritis of the knee. As we've mentioned previously, reaching agreement with the FDA on the SPA was our number one priority. "We look forward to initiating this trial as soon as possible and are excited to continue to work with all of the parties that have and will be instrumental in our development of this important cell therapy product."

Phase 3 data from a separate clinical trial in Korea by TissueGene's licensee, Kolon Life Science, Inc, is expected in September of 2015 with BLA submission to the Korean Ministry of Food and Drug Safety (MFDS) by later this year. "We anticipate commercialization of Invossa™ by early next year in Korea and look forward to its expansion in the Asian market," said Mr. Lee.

ABOUT TISSUEGENE, INC.

TissueGene, 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.

ABOUT SPECIAL PROTOCOL ASSESSMENTS (SPA)

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessment, please visit: http://1.usa.gov/1w2ODoJ.

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