

Kolon TissueGene To Expand Indications For TG-C

ACTIVITIES ARE UNDERWAY TO INITIATE US PHASE II IN HIP OSTEOARTHRITIS

ROCKVILLE, Md., Dec. 3, 2021 /PRNewswire/ -- Kolon TissueGene, Inc. ("the Company"), a leader in advanced cell and gene therapies, announced today that the FDA has allowed the Company to proceed with initiation of a Phase II clinical trial in osteoarthritis (OA) of the hip. Kolon TissueGene has begun activities to initiate the Phase II trial.

FDA has allowed the Company to proceed with initiation of a Phase II clinical trial in osteoarthritis (OA) of the hip.

The Phase II, multicenter, randomized, double-blind, placebo-controlled trial will enroll about 255 patients at over 25 clinical sites across the United States. During the trial, the company will assess the effectiveness, evaluate the safety, and find the optimal dose for TG-C in hip OA. The trial will assess pain improvement in hip OA and measure TG-C

effects on structural features of the hip joint via X-ray, as well as assess quality-of-life improvements.

"Building upon the success and long term efficacy we have seen in our clinical trials for TG-C in knee osteoarthritis, hip OA is a natural progression as the next indication for TG-C, our novel cell and gene therapy," said Dr. Moon Jong Noh, Co-CEO of Kolon TissueGene.

"Current hip OA patients need more options in addition to analgesics and opioids, which just treat pain, and have well-known risks and side effects. A therapy which could last well longer than steroid injections, another current option for hip OA, TG-C would be a welcome addition to the arsenal for hip OA patients, stated Dr. Sung Han, Co-CEO of Kolon TissueGene.

About Kolon TissueGene, Inc.

Kolon TissueGene, Inc., is an advanced cell therapies company that has developed a first-in-class cell and gene therapy targeting OA of the knee. Kolon TissueGene's lead product, TG-C, is an allogeneic cell and gene therapy. The Company has plans for two pivotal Phase III clinical trials in knee OA in the U.S., the first under a Special Protocol Assessment (SPA) agreement reached with the U.S. Food and Drug Administration (FDA). Information about the trials can be found at the National Institutes of Health registry, www.clinicaltrials.gov. For additional information about Kolon TissueGene, Inc., please visit www.tissuegene.com.


About TG-C

TG-C [TissueGene-C] is a first-in-class cell and gene therapy targeting OA of the knee through a single intra-articular injection. Clinical trials held in the U.S. and abroad have demonstrated pain relief and increased mobility, as well indicators towards decreased progression of OA and improvements in joint structure. The allogeneic drug could provide an alternative to traditional treatment and surgery, or delay the progression of OA to minimize the need for multiple surgical interventions. In a concluded U.S. Phase II clinical trial in knee

OA, Kolon TissueGene demonstrated a two-year improvement of pain and function. The company seeks to continue to support these results through its planned national U.S. Phase III clinical trial and expand the indication to hip OA.

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