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KOLON TISSUEGENE

KOLON TISSUEGENE COMPLETES PATIENT DOSING IN TWO PIVOTAL US PHASE III CLINICAL TRIALS FOR TG-C

- Completed patient dosing in US Phase 3 clinical trials.
- There will be a two-year follow-up period, followed by submission of the Biologics License Application (BLA) to permit marketing of TG-C once approved.

ROCKVILLE, Md., July 11, 2024 /PRNewswire/ -- Kolon TissueGene, Inc. ('the Company") announced today that patient dosing has been completed on the US Phase 3 clinical trials for Knee Osteoarthritis. Since resuming patient recruitment in November 2021, the Company has completed 2 large clinical trials involving 1,066 patients in about 30 months.

Completion of patient dosing is a big milestone which enabled the Company to complete the pivotal Phase 3 clinical trials. The Company worked diligently with the US Food and Drug Administration (FDA) to get the clinical hold lifted in April 2020, which allowed resumption of the Phase 3 clinical trials in the US. The clinical hold was successfully lifted through extensive research based on scientific data on TG-C and an intensive regulatory review process.

Even though there were difficulties in the Phase 3 clinical trial process such as significant delays of the clinical studies in the US due to the global pandemic, the Company was able to complete patient dosing in the Phase 3 clinical trials with the determination and conviction to succeed in developing the world's first and only cell and gene therapy for osteoarthritis of the knee.

During the patient recruitment process, approximately 6,700 patients signed up to participate in the Phase 3 clinical trials. Among them, more than 1,000 patients met eligibility criteria and were enrolled in the Phase 3 clinical trials.

In accordance with the protocol, the Company will continue a two-year follow-up on all dosed patients to assess the safety and efficacy after TG-C administration. The results of the Phase 3 clinical trials will be published at the end of the two-year follow-up period.

During the follow-up period, the Company will prepare the BLA submission package for the US FDA in order to obtain marketing authorization of TG-C in the US. The Company has already begun preparations related to commercial production (manufacturing) and is collaborating with Lonza, the world's largest pharmaceutical CDMO.

"We expect the Phase 3 clinical trials to provide positive results, similar to the successfully completed Phase 2 clinical trial in the US" said Moon Jong Noh, PhD, CEO of the Company, adding, "When the Phase 3 clinical trials are successfully completed, we will start discussions with potential partners for commercial sales and marketing along with completion and submission of the BLA for product approval." In addition, he said, "All executives and employees will do their best to repay all customers, shareholders, and others

who have trusted and waited for the Company for a long time with meaningful results."

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. The Company's lead product, TG-C, is an allogeneic cell and gene therapy. The Company is conducting Phase 3 clinical trials in the US under a Special Protocol Assessment (SPA) agreement reached with the US 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 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 US and abroad have demonstrated pain relief and increased mobility, as well indicators towards decreased progression of OA and improvements in joint structure. The allogeneic (off-the-shelf) 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 US Phase 2 clinical trial, Kolon TissueGene demonstrated a two-year improvement of pain and function. The Company seeks to continue to support these results through its Phase 3 clinical trials. In addition, the Company has designed the trials to seek a disease-modifying osteoarthritis drug (DMOAD) designation for TG-C from the US FDA—potentially making TG-C the first therapy to receive such a DMOAD label.

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