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KOLON TISSUEGENE

Kolon Tissuegene Announces Plans To Resume US Phase III Clinical Trial For TG-C

Activities Are Underway To Reinitiate The US Phase III

ROCKVILLE, Md., April 13, 2020 /PRNewswire/ -- Kolon TissueGene, Inc. (the "Company"), a leader in advanced cell and gene therapies, announced today that the Clinical Hold issued by the FDA in April 2019 has been lifted effective April 10, 2020, and that the Company can continue with its knee osteoarthritis (OA) phase III clinical trial. The trial had been suspended due to product identity concerns. Kolon TissueGene has begun activities to resume the phase III trial and reinitiate enrollment later this year.

Two (2) pivotal phase III trials for US approval of TG-C will enroll close to 1,020 patients at over 50 clinical sites across the United States. The trial investigators include orthopedic surgeons, rheumatologists, and pain specialists. During the trials, the Company will assess pain and function endpoints, as well as MRI, X-Ray and liquid biomarkers. In addition to significant pain and function improvements, the Company has designed the trials for TG-C to achieve a Disease Modifying Osteoarthritis Drug or "DMOAD" designation.

"A novel cell and gene therapy that achieves 2 years of pain relief and improvement in function as well as a delay in the need for knee surgery would fill a significant treatment gap in the treatment of OA," said Dr. Moon Jong Noh, Co-CEO of Kolon TissueGene.

"OA is a debilitating disease without any current therapies being able to slow the progression of the disease and improve a patient's quality of life," stated Dr. Sung Han, Co-CEO of Kolon TissueGene. "The FDA's decision moves us closer to providing an important treatment to OA patients who currently have few, if any, options in improving their symptoms of pain and lack of mobility."

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 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 as 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, 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.

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