July 6, 2018

KOLON TISSUEGENE

Kolon TissueGene To Start US Phase III Clinical Trial For Invossa™

FDA GIVES KOLON TISSUEGENE THE GO-AHEAD FOR PHASE III PATIENT ENROLLMENT

ROCKVILLE, Md., July 6, 2018 /PRNewswire/ --Kolon TissueGene, Inc. ("the Company"), a leader in advanced cell and gene therapies, announced today that Clinical Hold issued by the FDA has been lifted effective July 5, 2018 and that the Company now has FDA Approval to move forward with its clinical trials involving patients diagnosed with knee osteoarthritis (OA).

The pivotal phase III trials for US approval of Invossa will enroll close to 1,020 patients at over 50 clinical sites across the United States. In addition to demonstrating significant pain and functional improvements, the Company has designed the trials for Invossa™ to achieve a Disease Modifying Osteoarthritis Drug or "DMOAD" designation. A DMOAD designation would be a unique designation in the armamentarium towards treatment of knee OA.

Current OA patients suffer through many years of debilitating pain and reduced quality of life. A single injection of Invossa could lead to more than 2 years of productive and pain free mobility, without the immediate need for surgery, and fill in this significant treatment gap.

"The decision by the US FDA today moves us one step closer to providing relief to millions of OA patients in the US and around the world. As one of the fastest growing unmet medical needs, where patients have few, if any options, a therapy that provides pain relief and greater mobility for OA patients without the immediate need for risky surgery is a growing and urgent public health issue," said Mr. Woosok Lee, 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, Invossa™, is an allogeneic cell and gene therapy. The Company is preparing for Phase III clinical trials in the U.S. 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.

In November 2017, Kolon TissueGene, Inc. successfully completed an offshore initial public offering and was listed on the Korean stock market (KOSDAQ: 950160). Kolon TissueGene's securities have not been and will not be registered under the U.S. Securities Act of 1933, as amended (the "Securities Act") and may not be offered or sold within the United States or to, or for the account or benefit of, U.S. persons except in certain transactions exempt from the registration requirements of the Securities Act.

About Invossa™

Invossa™ 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 (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 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. In addition, the company has designed the trial to seek a disease-modifying osteoarthritis drug (DMOAD) designation for Invossa™ from the U.S. Food and Drug Administration (FDA)—potentially making Invossa the first therapy to receive such a DMOAD label. In July 2017, Kolon Life Science, Inc., Kolon TissueGene's exclusive licensee for Asia, received marketing approval from the South Korea Ministry of Food & Drug Safety (MFDS) for Invossa-K Inj.

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