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Korea Approves the World's First Cell and Gene Therapy for Knee Osteoarthritis

Invossa-K Inj. Licensed for Sale in Korea as the First Step of a Global Launch Strategy

ROCKVILLE, Md., July 12, 2017 /PRNewswire/ -- TissueGene, Inc. ("TissueGene"), a Maryland-based regenerative medicine company, announced today that Kolon Life Science, TissueGene's exclusive licensee for Asia, including Korea, has received marketing approval for Invossa-K Inj., the world's first cell and gene therapy for degenerative arthritis from the Korea Ministry of Food and Drug Safety (MFDS).

Kolon Life Science filed for a Biologics License Application (BLA) for Invossa-K Inj. with MFDS in August 2016 based on efficacy results from its Phase III clinical trials conducted at 12 major university hospitals in Korea. Invossa-K Inj. will be manufactured by Kolon Life Science, and marketed by Mundipharma and Kolon Pharmaceuticals for the Korean market.

"We are excited to launch the world's first cell and gene therapy for knee osteoarthritis and potentially the world's first disease-modifying osteoarthritis drug (DMOAD)," stated Mr. Woosok Lee, CEO of TissueGene. "This approval is the first critical step towards a global launch for this innovative, novel cell and gene therapy technology that will address one of the most pressing unmet medical need affecting millions of people suffering from osteoarthritis worldwide."

Invossa™ is a first-in-class cell and gene therapy drug designed to conveniently and effectively treat osteoarthritis of the knee through a single intra-articular injection. Clinical trials completed in Korea and on-going in the US have demonstrated pain relief, increased mobility, and potentially game-changing improvements in joint structure – offering substantial relief and convenience for osteoarthritis patients who would otherwise be in need of surgery.

Through its national US Phase III clinical trials, TissueGene will be using the results to seek a DMOAD designation for Invossa™ from the US Food and Drug Administration (FDA), potentially making Invossa™ the first and only cell and gene therapy for osteoarthritis of the knee.

In November last year, Kolon Life Science signed a license agreement with Mitsubishi Tanabe Pharmaceutical Corporation, and Mitsubishi Tanabe Pharma is proceeding with the preparation of clinical trials through its exclusive development and commercialization rights in Japan.

TissueGene, Inc.

TissueGene, Inc., is a Maryland-based regenerative medicine company specializing in cell and gene therapy. TissueGene's lead product is Invossa™, an allogeneic, cell and gene therapy for osteoarthritis of the knee that is preparing for Phase III clinical trials in the US pursuant to a Special Protocol Assessment (SPA) agreement reached with the U.S. Food

and Drug Administration. Information about the trials can be found at the NIH registry, [ww.clinicaltrials.gov](http://www.clinicaltrials.gov). For additional information about TissueGene, Inc., please visit www.tissuegene.com.

Kolon Life Science

Kolon Life Science has been developing innovative cell and gene therapies including Invossa K Inj., the world's first cell-mediated gene therapy for osteoarthritis, since its founding in 2000. In addition to its biopharmaceuticals business, the company is also engaged in the business of providing active pharmaceuticals ingredients (API), eco-chemicals including antimicrobials for personal-care and industrial applications, as well as water-treatment solutions. For more information, please visit www.kolonls.co.kr/eng

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