

Kolon TissueGene to Expand License Agreement for INVOSSA™ with Kolon Life Science

INVOSSA™ to be marketed in Saudi Arabia and UAE

Rockville, Maryland, June 22, 2018 – Kolon TissueGene, Inc. (“the Company”), a leader in advanced cell and gene therapies, announced today that it will add two key Middle Eastern countries to the existing license agreement with Kolon Life Science, Inc. for the commercial sale of Invossa-K Inj™, the world’s first approved cell and gene therapy for knee osteoarthritis. As the exclusive licensee for the Asia territory, Kolon Life Science is now positioned to enter a growing market in the Middle East.

The two countries to be added are Saudi Arabia and United Arab Emirates (UAE), and the licenses will be granted until 2024. Under the terms of the agreement, Kolon TissueGene will receive sales-based royalties from Kolon Life Science. After 2024, Kolon TissueGene will consider whether to introduce Invossa™ in these countries following regulatory approval by the U.S. Food and Drug Administration (FDA).

In July 2017, Kolon Life Science, received marketing approval from the South Korea Ministry of Food & Drug Safety (MFDS) for Invossa-K Inj. The product is now available in the South Korean market and being marketed by Mundipharma and Kolon Pharmaceuticals.

In the US, Kolon TissueGene is scheduled to run pivotal Phase III trials for US approval of Invossa for knee osteoarthritis. In addition to demonstrating significant improvements in pain relief and mobility, the trials will be designed for Invossa™ to achieve a Disease Modifying Osteoarthritis Drug or “DMOAD” designation. Such a designation by the FDA would be a first for any osteoarthritis drug approved in the US.

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 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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