#### Press release

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# Mitsubishi Tanabe Pharma Takes on the Challenge of Cell Therapy

with the Conclusion of an Invossa<sup>®</sup> Licensing Agreement with Kolon Life Science Aiming for therapy that addresses unmet medical needs in the treatment of knee osteoarthritis

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka, Japan; President and Representative Director: Masayuki Mitsuka) and Kolon Life Science, Inc. (KLS) (Head Office: Gwacheon, Republic of Korea; CEO, Woo-Sok Lee) have concluded a licensing agreement for Invossa<sup>®</sup>, a cell therapy product for improvement of symptoms of knee osteoarthritis. Through this agreement, Mitsubishi Tanabe Pharma will acquire exclusive development and commercialization rights for Invossa<sup>®</sup> in Japan.

Invossa<sup>®</sup> is an allogeneic human chondrocyte product and was discovered by TissueGene, Inc. (TGI), an affiliate of KLS. Intra-articular injection of Invossa<sup>®</sup> improves pain in knee osteoarthritis patients. In addition, Invossa<sup>®</sup> is expected to delay the progression of cartilage destruction. KLS has completed phase 3 clinical trials in Korea, and in July 2016 KLS filed an application with Ministry of Food and Drug Safety in Korea for biologic manufacturing approval. In the United States, TGI has completed phase 2 trials, and preparations for phase 3 trials are under way. Mitsubishi Tanabe Pharma plans to advance development in Japan for an indication of knee osteoarthritis, including evaluation of delaying in the progression of cartilage destruction.

The Company is aiming to address unmet medical needs for patients with knee osteoarthritis through Invossa® as well as MT-5547 (NGF antibody, fasinumab), which is currently under development.

Under this contract, the Company will make an upfront payment to KLS of ¥2.5 billion. In addition, KLS will receive development and sales milestone payments and running royalties in accordance with the level of sales. The influence of this contract on the Company's results has already been reflected.

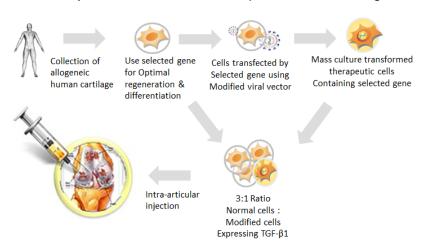
In accordance with the key concept of the Medium-Term Management Plan 16-20: Open Up the Future, moving forward Mitsubishi Tanabe Pharma will take on challenges to foster the delivery of new drugs.

There's no impact to the current financial forecast.

# About Invossa®

Invossa<sup>®</sup> is a type of cell therapy. The source for Invossa<sup>®</sup> is cartilage tissue collected from allogeneic donors. Cartilage chondrocytes that have been isolated and cultured are combined with genetically engineered cartilage chondrocytes transduced with transforming growth factor TGF-β1, and the therapy is administered through intra-articular injection. Invossa<sup>®</sup> was developed as a treatment agent

for knee osteoarthritis. The knee osteoarthritis is primarily caused by change in the joint due to aging-related loss of elasticity in joint cartilage, which is worn away by physical friction. The main symptoms include knee pain, swelling, and limits on range of movement. Current treatment agents are principally aimed at pain relief, and there are no agents with indications for delaying the progression of the disease.



Invossa® increases the engraftment of the cultured cartilage chondrocytes, which are administered through intra-articular injection at the same time as the genetically engineered cartilage chondrocytes transduced with TGF- $\beta$ 1. In addition, these chondrocytes improve cartilage metabolism abnormalities. In this way, Invossa® provides effective pain relief, and furthermore it is expected to delay the progression of cartilage damage. In the phase 3 clinical trials in Korea implemented by KLS, with these results, KLS filed an application for biologic manufacturing approval with Korea's Ministry of Food and Drug Safety in July 2016

### **Overview of Mitsubishi Tanabe Pharma**

Mistubishi Tanabe Pharma, which was founded in 1678, has its headquarters in Doshomachi, Osaka, which is the birthplace of Japan's pharmaceutical industry. With business centered on ethical pharmaceuticals, Mitsubishi Tanabe Pharma is a well-established company and has the longest history of any listed company in Japan\*. In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Company formulated the key concept of Open Up the Future under the Medium-Term Management Plan 16-20. Through the discovery of drugs that address unmet medical needs, centered on its priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world.

# http://www.mt-pharma.co.jp/

# **Overview of Kolon Life Science**

Kolon Life Science has been developing innovative cell and gene therapies including Invossa, 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 <a href="http://www.kolonls.co.kr/eng/">http://www.kolonls.co.kr/eng/</a>

<sup>\*</sup> Research by TOKYO SHOKO RESEARCH, LTD.