## Notice regarding the launch of Collategene® intramuscular injection 4 mg, an HGF gene therapy product

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka City; President & Representative Director: Masayuki Mitsuka) and AnGes, Inc. (Head Office: Ibaraki City, Osaka; President & Representative Director: Ei Yamada) announced today that an NHI drug price listing has been obtained for Collategene® intramuscular injection 4 mg (Active ingredient: beperminogene perplasmid), an HGF gene therapy product for critical limb ischemia in Japan. Collategene® will be launched on Tuesday, September 10, 2019 in Japan.

Collategene® has been a key project for AnGes, which has worked on Collategene® since its establishment. On March 26, 2019, AnGes received conditional, time-limited approval for Collategene® for the improvement of ulcers in patients suffering from Peripheral artery disease. Collategene® is the first gene therapy product to be approved in Japan. Collategene® is a DNA plasmid that expresses hepatocyte growth factor (HGF). It is introduced into the lower limb muscle cells, which are the target cells, transcribed and translated in the muscle cells, and then HGF is produced and secreted. Through angiogenesis effect of HGF, the number of blood vessels and the local blood flow are increased at the site of the ischemia, thereby improving ulcers.

In June 2015, Mitsubishi Tanabe Pharma and AnGes concluded an exclusive sales rights agreement for sales of HGF gene-therapy products targeting peripheral arterial diseases in Japan. Mitsubishi Tanabe Pharma will be in charge of sales and marketing of Collategene®. The approval of Collategene® has conditions and a time limit, and acquisition of official marketing approval will require the implementation of a post-approval evaluation within the time limit of five years. Mitsubishi Tanabe Pharma has been commissioned by AnGes to conduct a confirmatory study as the post-approval evaluation.

Moving forward, by aiming to acquire official marketing approval for Collategene, Mitsubishi Tanabe Pharma and AnGes will continue working to provide a new treatment option for ulcers in patients suffering from Peripheral artery disease that performance of revascularization is difficult. We will also strive to promote appropriate use of Collategene, and help to increase the QOL of patients with critical limb ischemia.

## **About Mitsubishi Tanabe Pharma Corporation**

Mitsubishi 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 pharmaceutical 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 — immuno-inflammation, diabetes and kidney, central nervous system, and vaccines — Mitsubishi Tanabe Pharma will strive to contribute to the health of patients around the world.

## **About AnGes**

AnGes is a biopharmaceutical company focused on the development and commercialization of gene-based medicines including gene therapy and oligonucleotide molecules. In addition to HGF plasmid, which is the company's lead product, AnGes is developing NF-kB Decoy oligonucleotide for the treatment of inflammatory diseases. The company has facilities located in Tokyo and Osaka, Japan and is listed on the Mothers Stock Exchange in Tokyo, a market for emerging companies.

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