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AnGes Obtains Conditional Approval in Japan for HGF Gene Therapy to Treat Critical Limb Ischemia

AnGes, Inc., a biopharmaceutical company focused on developing innovative gene-based medicines for treating serious diseases, announced today that they have obtained conditional approval ("Approval with Conditions and Time Limit") from the Japanese Ministry of Health, Labour and Welfare (MHLW) for HGF plasmid to treat patients with critical limb ischemia (CLI).

HGF plasmid is the first gene therapy product to be approved in Japan, for the improvement of ulcers in patients suffering from chronic arterial occlusion (arteriosclerosis obliterans and Buerger's disease) who have had an inadequate response to standard pharmacotherapy and who experience difficulty in undergoing revascularization. AnGes applied for marketing approval to the MHLW in January 2018 based on positive results from the randomized, placebo-controlled phase three trial and investigator-led clinical study conducted in Japan. HGF plasmid is one of the first gene therapy products to be approved for a non-genetic disease with chronic and progressive symptoms.

In accord with the conditions of the approval, AnGes will conduct a confirmatory study for all patients who receive treatment with HGF plasmid under the conditional approval and will submit an application to lift the conditions within five years.

AnGes has granted to Mitsubishi Tanabe Pharma Corporation the marketing rights to HGF plasmid in Japan and the U.S.A. for treating peripheral arterial diseases including CLI. Mitsubishi Tanabe is responsible for sales and marketing of the product.

About Critical Limb Ischemia (CLI)

CLI is caused by decreased arterial blood flow in a lower limb due to arteriosclerosis, for which risk factors include diabetes, hypertension and smoking. The disease is estimated to newly affect approximately 500,000 patients every year in the U.S.A. CLI causes severe pain and/or ulcers, often leading to limb amputation when there are no remaining therapeutic options, and consequently quality of life for such patients deteriorates dramatically.

About HGF plasmid

HGF plasmid is a DNA plasmid which encodes human Hepatocyte Growth Factor (HGF) gene, an angiogenic (new blood vessel growth) factor. It is administered intramuscularly into a lower limb and is anticipated to stimulate growth of new blood vessels leading to improved blood flow.

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.

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 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.

Forward-Looking Statement

This news release contains forward-looking statements. Any forward-looking statements are based on the current expectations of the company's management and are subject to significant risks and uncertainties.

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Disclaimer: This is a translation of a news release published in Japanese. In the event of any deviations between the two language versions, the original document in Japanese shall take precedence.

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