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AnGes, Inc.

AnGes Submits Application for Marketing Approval to PMDA for HGF gene therapy for Critical Limb Ischemia

AnGes, Inc., a biopharmaceutical company focused on developing innovative gene-based medicines for serious diseases, announced today the submission of an application for marketing approval to the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan for HGF plasmid, an investigational gene therapy for the treatment of critical limb ischemia (CLI), the most severe condition of peripheral arterial disease.

The submission is based on the positive results from the randomized, placebo-controlled phase 3 trial and investigator-led clinical study conducted in Japan. AnGes anticipates being granted conditional approval under the regulatory scheme of “Approval with Conditions and Time Limit” for regenerative medicines. The review process is expected to take approximately one year. HGF plasmid has the potential to be one of the first gene therapy products to be approved for a non-genetic disease with chronic conditions.

AnGes grants to Mitsubishi Tanabe Pharma Corporation the marketing rights to HGF plasmid for peripheral arterial diseases including CLI in Japan and the US. Once approved, Mitsubishi Tanabe will be responsible for the sales and marketing of the product.

About Critical Limb Ischemia (CLI)

CLI is caused by worsened arterial blood flow in the lower limb due to arteriosclerosis, for which risk factors include diabetes, hypertension and smoking. The disease is estimated to affect approximately 500,000 patients newly every year in the US. CLI causes severe pain and/or ulcers leading to amputation when there is no therapeutic option left, and thus quality of life in patients deteriorates severely.

About HGF plasmid

HGF plasmid is a DNA plasmid that encodes human Hepatocyte Growth Factor (HGF) gene, an angiogenic (growing new blood vessels) factor. It is administered intramuscularly into the lower limb and is expected to help grow 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 medicines. In addition to HGF plasmid, the company's lead product under development, AnGes develops NF-kB Decoy oligonucleotide for the treatment of inflammatory diseases. The company is located in Tokyo and Osaka, Japan and is listed on Mothers of Tokyo Stock Exchange, a market for emerging companies.

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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