April 15 2016

AnGes MG, Inc.

AnGes Completes Patient Enrollment for Phase 1/2 Clinical Trials of Gene Therapy with HGF Plasmid in Primary Lymphedema

AnGes MG, Inc. ("AnGes") announced that patient enrollment for the Phase 1/2 clinical trials of HGF (Hepatocyte Growth Factor) Plasmid for Primary Lymphedema is now complete. AnGes started the Phase 1/2 clinical trials in October 2013.

The Phase 1/2 clinical trials investigate the safety and efficacy of HGF Plasmid in about 20 subjects with primary lymphedema. HGF Plasmid is administered intramuscularly in the lower limb of the subject with lymphedema. The study assesses the changes in edema volume and the quality of life over time for a period of 1 year.

Lymphedema is an intractable disease that compromises the lymphatic system and prevents lymphatic fluid from returning to the lymph vessels, causing severe swelling and fluid retention in the limbs. There are two types of lymphedema: 1) "primary lymphedema" for which the pathogenesis is unidentified, and 2) "secondary lymphedema" which can occur after the dissection of the lymph node in cancer surgery. There is no established means for effectively treating lymphedema as it chronically progresses and exacerbates over time, decreasing patients' quality of life. For these reasons, the development of a new treatment method is highly desired.

HGF Plasmid is a DNA Plasmid encoding HGF gene. When administered, it produces HGF proteins that play important roles in the regeneration of tissues and organs in the body. HGF Plasmid is one of the core products of AnGes, and progress has been made in developing a treatment of peripherial arterial disease involving the use of HGF's angiogenesis function. The lymphangiogenesis function (creation of new lymphatic vessels) of HGF Plasmid has already been confirmed in preclinical studies. The ongoing Phase 1/2 clinical study represents the first attempt in the world to treat lymphedema with gene therapy. In the future, HGF plasmid is expected to become a standard form of treatment.

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Disclaimer: This is a translation of the news release posted in Japanese. If there is any deviation between the two language versions, the original document in Japanese shall take precedence.

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