



July 30, 2012

AnGes MG, Inc.

**AnGes MG Submits an IND Application for
Collategene™ (HGF DNA Plasmid)
- Initiation of the World's First Clinical Trial on Gene Therapy for
Lymphedema -**

AnGes MG, Inc. ("AnGes") announced today that their IND application for Collategene™ (HGF DNA Plasmid) as a treatment for primary lymphedema has been accepted by Pharmaceuticals and Medical Devices Agency (PMDA).

The clinical trial is planned to ensure Proof of Concept (POC) study for primary lymphedema and is the first Phase I/II trial to be conducted with patients. In this trial study, Collategene™ will be administered intramuscularly to patient's affected legs which are swollen by more than 20% compared to the healthy legs, and the changes to the volume of edema will be assessed to investigate safety and efficacy of Collategene™.

Lymphedema is an intractable disease in which compromised lymphatic system causes severe swelling and fluid retention in limbs by preventing lymphatic fluid from returning to lymph vessels. There are two types of lymphedema: 1) "primary lymphedema" which the pathogenesis is unidentified, and 2) "secondary lymphedema" which occurs due to aftereffects of lymph node dissection in e.g. cancer surgery. The existing treatment for lymphedema is mainly focused on complex decongestive therapy by massaging the affected limbs and using compression garments. However, this treatment is symptomatic and should be continued throughout the life. Furthermore, there has been an increase in lymphedema cases among elderly patients in recent years who are unable to perform physical treatment on their own. For these reasons, a development of a new treatment for lymphedema is highly desired.

Development for the treatment of Critical Limb Ischemia using Collategene™ has been ongoing at AnGes and now the research development of lymphedema treatment utilizing Collategene™'s action to promote lymph vessel formation has begun. With the confirmation received from the Ministry of Health, Labor and Welfare (MHLW) on July 18, 2012 that clinical trial plan of Collategene™ in lymphedema complies with the guideline for confirmation application, AnGes is ready to initiate the clinical trial for lymphedema treatment with Collategene™, the world's first effort in treating lymphedema utilizing lymph vessel growth function. That being said, Collategene™ has a potential to become a radical treatment.

AnGes plans to initiate the clinical trial promptly after taking necessary procedures, and strive to pursue the development in order to provide the new treatment for patients who suffer from lymphedema.

Once the company completes the POC clinical trial with patients with primary lymphedema, AnGes plans to start with the development for secondary lymphedema. It is reported that secondary lymphedema occurs in about 30% of patients who underwent uterus cancer surgery, and 50% of patients who underwent breast cancer surgery. Based on these figures, it is estimated that more than 1 million patients are suffering from lymphedema in seven major industrialized nations, with an approximate market size of 50 billion yen a year.

This trend will have no effect on the business performance for the fiscal year of 2012.

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(Reference)

Gene Medicine

A drug which utilizes gene or a part of gene as active ingredient.

HGF (Hepatocyte Growth Factor)

A growth factor developed from hepatocytes; in addition to blood vessel regeneration, it initiates various processes necessary for tissue / organ regeneration during organ formation (organogenesis).

Lymphedema

Lymphedema is an intractable disease in which compromised lymphatic system causes severe edema in limbs by preventing tissue fluid from going back to lymph vessel, causing it to be retained under the skin. There are two types of lymphedema; 1) "primary lymphedema" which the pathogenesis is unidentified, and 2) "secondary lymphedema" which occurs due to aftereffects of lymph node dissection in cancer surgery, etc. There is no effective treatment method established for lymphedema while it chronically progresses and is exacerbated over time, declining patients' quality of life.

Peripheral Arterial Disease

Narrowed or blocked peripheral blood vessels in the four limbs causes ischemic condition in muscle and skin tissues, with the following symptoms: a feeling of paralysis, coldness, intermittent claudication, ulcer of lower limbs (thrombic disease) or rest pain. It includes arteriosclerosis obliterans and Buerger's disease.

Proof of Concept (POC)

A proof of concept (POC) is a demonstration to verify that a fundamental finding or concept has the real-world application. In development of drugs, POC refers to examination of a drug candidate compound for a certain disease in real patients after its effect was indicated in animal models.

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

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