



October 4, 2013

AnGes MG, Inc.

**Phase 1/2 Study of Collatogene[®] (HGF Gene Therapy) Starts in Japan
– The World’s First Gene Therapy for Lymphedema –**

AnGes MG, Inc. (AnGes) announced that a clinical study of Collatogene[®] (HGF gene therapy) for the treatment of primary lymphedema has started at the contracted trial site. This study is the world’s first effort in treating lymphedema with gene therapy.

The existing treatment for lymphedema is mainly focused on complex decongestive therapy, such as massaging the affected limbs and using compression garments. However, this treatment is symptomatic and should be continued throughout the lifetime. Furthermore, there has been an increase in lymphedema among elderly patients, and elderly patients have difficulties in performing physical treatment on their own. For these reasons, development of a novel treatment for lymphedema is highly desired.

Collatogene[®] may provide a causal therapy against lymphedema, and is expected to be a first-in-class lymphedema drug utilizing the regenerative potential of the lymph vessel.

This Phase 1/2 study targets “primary lymphedema,” for which the pathogenesis is unidentified, and aims to establish the proof of concept (POC). In this study, the drug is administered intramuscularly to a subject’s limb, which is swollen compared to the healthy limb, and the changes to the edema volume will be assessed to investigate safety and efficacy of Collatogene[®].

Ei Yamada, the CEO and president of AnGes, says “We are very pleased to announce the initiation of the first-in-human study of Collatogene[®] as a treatment for lymphedema. While Collatogene[®]’s development has been advancing for the treatment of peripheral arterial disease, we were also pursuing the development for lymphedema, with a focus on Collatogene[®]’s action to regenerate lymph vessel formation. This study targets primary lymphedema, which affects a few thousand patients in Japan. However, the number is significant for patients who are living with cancer-related secondary lymphedema. It is reported that cancer-related secondary lymphedema occurs in 100,000 to 200,000 people in the United States (US) and Europe every year. We intend to expand our development to secondary lymphedema, with an aim to provide a new treatment for patients.”

The effect of this event has already been included in the business performance forecast for the fiscal year 2013.

(Glossary)

Gene medicine

A drug which utilizes a gene or part of a gene as its 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).

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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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