



February 7, 2014

AnGes MG, Inc.

A Global Phase III Trial of Collategene[®], a Drug for Ischemic Disease, to Start During the Second Quarter of 2014 in the United States and Europe

AnGes MG, Inc. (AnGes), announced today that the global Phase III trial of its ischemic disease drug, Collategene[®] (DNA plasmid with hepatocyte growth factor [HGF] gene), is expected to commence during the second quarter of 2014.

Regarding Collategene[®], AnGes has achieved favorable results from the multiple clinical trials conducted in patients with critical limb ischemia (CLI) in Japan and the United States (US). The global Phase III trial is a pivotal study to confirm the efficacy and safety of Collategene[®] in a large number of patients, and to obtain the data necessary for a new drug application in the US and Europe.

The trial will enroll approximately 500 patients with CLI and will be conducted at multiple sites in North America, Europe, and South America. It is a placebo-controlled and double-blinded study*¹, which will evaluate improvements in lower limb amputation rates and death rates in the Collategene[®]-administered group compared to placebo group after a certain period of time. The trial sites will open from the second quarter of 2014, and the first patient is expected to be enrolled in the third quarter of 2014.

This global Phase III trial will not include Japan, where AnGes plans to undertake a separate development plan utilizing a newly enacted conditional approval system*² for regenerative medicines. Under the new system (amendments to Japanese Pharmaceutical Affairs Act expected to be enforced in the autumn of 2014), if AnGes achieves required conditions as planned, it may seek marketing approval in Japan before the US or Europe.

CLI is a serious condition in which poor blood circulation causes severe pain, ulcers, and necrosis, and which may ultimately require amputation of the lower limb. Effective treatment is currently unavailable for patients who are ineligible for existing intravascular treatments, such as balloon-catheter treatment or bypass surgery. Collategene[®], a genetic medicine, is believed to treat CLI with its innovative mechanism; injection of the HGF gene plasmid to the affected limb induces growth and development of new blood vessels, and, as a result, restores blood circulation. In the US, there are 500,000 patients with CLI, with the potential market estimated to be 5 billion dollars (USD).

AnGes believes that approval of Collategene[®] means that a new treatment option can be provided to patients with CLI, and that the company can obtain a remarkable revenue stream. AnGes has formed partnerships with Mitsubishi Tanabe Pharma Corporation for exclusive marketing rights in the US, and Daiichi Sankyo Company, Ltd., for development and marketing rights in Japan for Collategene[®] as a treatment of peripheral arterial diseases including CLI. Under the partnership agreements, AnGes holds the rights to receive performance-based milestone payments and sales-based payments.

Development of Collategene[®] as a treatment for CLI has been a core project since the company's establishment, and it is expected to become the mainstay of future growth. The initiation of a global Phase III clinical trial is an important milestone in achieving the company's vision of becoming "a global leader in genetic medicine."

The effect of this event on AnGes's business performance for the fiscal year ending in December 2014 is included in the forecast published on the "Consolidated Financial Report for the Year Ending December 31, 2013," which was announced today.

*1 Double-blinded study

Double-blinding is an experimental procedure used to obtain reliable data by guarding placebo effects and experimenter bias. Subjects (patients), doctors, staff, and the sponsor (company) are unaware of which of the subjects are being treated with the investigational drug and which of the subjects are receiving placebo.

*2 Conditional approval system

This system allows conditional approval for a regenerative medicine and other product, including genetic medicines, based on partial clinical trial data. Full approval will be given when additional clinical data are obtained after the conditional approval. This new system was included in the amendments to Japanese Pharmaceutical Affairs Act enacted in November 2013, with the aim of promoting early approval of regenerative medicines, and it is expected to be enforced in autumn 2014 in Japan.

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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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