

August 19, 2013 AnGes MG, Inc.

Resumption of Development of Collategene® in Japan

AnGes MG Inc. ("AnGes") was looking for a favorable opportunity to further promote the development of Collategene® which is the Company's most important project and Japanese gene therapy in Japan. The proposed amendment to the Pharmaceutical Affairs Law was submitted by the government which includes a new conditional approval system corresponding to the practical use of gene therapy at an early stage. In consideration of these situations, AnGes resumed the development of Collategene® in Japan.

The establishment of rules for approval based on the characteristics of "products including regenerative medicine" was included in the proposed amendment to the Pharmaceutical Affairs Law as one of the major amendments. "Products including regenerative medicine" also include gene therapy. This is for the early practical use of regenerative medicine and other products including gene therapy aimed at establishing a conditional approval system to give tentative approval at an early stage and it is positioned as an advanced policy which delivers innovative new drugs fast to patients who suffer from diseases with no cure. The proposed amendment to the Pharmaceutical Affairs Law which was submitted to the Diet on May 24 is scheduled to be discussed in detail at an extraordinary Diet session this autumn.

Regarding the development of Collategene® in Japan, AnGes already applied for approval following its Phase 3 Trial but did not receive approval because the institutional environment was not set. In consideration of the past background, on the assumption that the system will be materialized, AnGes will promote a strategic development according to the conditional approval system.

Aside from the development in Japan, AnGes will continue preparations to be able to start the global Phase 3 Trial of Collategene® as a treatment for critical limb ischemia promptly.

###

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.

AnGes MG, Inc.
Corporate Communications
TEL:+81-3-5730-2641, FAX:+81-3-5730-2635
http://www.anges-mg.com
Email:info@anges-mg.com