



May 23, 2013
AnGes MG, Inc.

**AnGes submits an IND application for small-scale clinical study of
Collatogene[®] in the United States (US)**

AnGes Inc., the United States (US) subsidiary of AnGes MG, Inc. ("AnGes"), has submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) for the protocol of a small-scale clinical study of Collatogene[®] (DNA plasmid with the hepatocyte growth factor [HGF] gene). The small-scale study is a preliminary study to be conducted aside from the Phase III study of Collatogene[®] for the treatment of critical limb ischemia.

The small-scale clinical study is an open-label study targeting a small number of patients and has the same study design as the Phase III study. The objective of the small-scale study is to examine the feasibility, tolerability, and safety by the revised Special Protocol Assessment (SPA) protocol of the Phase III study, and biological distribution of the drug.

As announced by AnGes on March 4, 2013, AnGes Inc. received approval from the FDA for the revised SPA regarding the protocol for the Phase III clinical trial in which amendments were made to increase the probability of success.

SPA is a process by which a sponsor* reaches an agreement with the FDA on target disease, objective, trial design (endpoints, dosage and administration, case number), analytical method, etc., prior to the initiation of a Phase III clinical trial. The FDA recognizes that the proposed study is adequately designed to provide the necessary data that, depending upon outcome, could support a license application submission. This process is being used widely by biotech venture companies in Europe and the US to accelerate product launch in the market. AnGes expects that this SPA agreement will provide an opportunity for an early launch of Collatogene[®] in the US market.

This trend will have no effect on business performance for the fiscal year 2013.

* The term "sponsor" includes any sponsor or applicant interested in a Special Protocol Assessment.

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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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