



March 4, 2013
AnGes MG, Inc.

AnGes Group Receives FDA Approval of a Revised SPA for Phase III Clinical Trial for Collatogene[®], a Drug for Ischemic Disease Treatment

AnGes MG, Inc. ("AnGes") is pleased to announce that AnGes Inc., its US subsidiary, has received an approval from the U.S. Food & Drug Administration (FDA) for the revised SPA (Special Protocol Assessment) for the global Phase III clinical trial of Collatogene[®], a drug for Ischemic Disease. The revised SPA includes amendments in the previously accepted Phase III protocol which will support Collatogene[®]'s future product license application in the US market as a treatment for Critical Limb Ischemia (CLI).

Under the revised SPA for Collatogene[®], the Phase III trial protocol is amended to increase the probability of success, and it is expected to achieve higher effectiveness in the primary endpoints of amputation of lower limbs and improvement in death events of CLI patients.

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 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 America to accelerate product launch in the market. AnGes expects that this SPA agreement provides opportunity to an early launch of Collatogene[®] in the US market.

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

* The term "sponsor" includes any sponsor or applicant interested in 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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