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Agreement on SPA with the US FDA for Phase III Clinical Trial for CollategeneTM, a Drug for Ischemic Disease Treatment

AnGes MG Inc. announced today that AnGes Inc., the US subsidiary of AnGes MG Inc., has reached an agreement with the FDA on their SPA (Special Protocol Assessment) submission for the global Phase III clinical trial protocol (Europe and America) as of November 24, 2009.

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 MG Inc. expects that this SPA agreement provides opportunity to an early launch of CollategeneTM in the US market.

Based on the SPA agreement for CollategeneTM, poor option (high risk) patients with chronic and severe ischemia of the lower limb, who are eligible for revascularization by surgery with risk, are approved to be included in the trial. This will give more options to conduct the clinical trial with three to four times more target patients compared to other trials within the industry which only include no option patients* and shorter study duration. As a result, the number of patients eligible for the CollategeneTM treatment can be increased drastically.

*No option patients: the inability to receive an endovascular intervention or surgical bypass procedure due to inflow, conduit or outflow reasons or due to a severe and irreversible co-morbidity

Based on the SPA agreement, AnGes plans to accelerate negotiation with potential partner/s for conducting the Phase III clinical trial in Europe and America.