

October 29, 2007

AnGes MG, Inc.

**Academic Release of Data from Phase III Clinical Trial of
HGF Gene Therapy Conducted in Japan**

AnGes MG, Inc. announced today that the results of an interim analysis of Phase III clinical trial (**this study**) on HGF gene therapy (**AMG0001**) for peripheral arterial disease (arteriosclerosis obliterans) was released at the 48th Annual Meeting of Japanese College of Angiology held in Matsumoto City in Nagano Prefecture.

Outline of Announcement

[Summary of Study]

This study was a multicenter, double-blind, placebo-controlled comparative study conducted in 57 medical institutions nationwide. The target patients included were those with arteriosclerosis obliterans presenting Critical Limb Ischemia (CLI) of Fontaine grade III or IV who could not undergo revascularization and did not respond to conventional drug therapies. The eligible patients who met the inclusion criteria of the study protocol were randomized into either AMG0001 group or placebo group (2:1) and received intramuscular administrations of study drugs twice to their ischemic lesions in the lower limbs at 4-week intervals. The follow-up observation was performed for 8 weeks to monitor their post-dose conditions (treatment period: 12 weeks).

The primary endpoint for the efficacy evaluation was "Presence or absence of improvement in pain at rest or ischemic ulcer," and the improvement rates were compared between both groups after 12 weeks.

The efficacy evaluation was performed in 40 patients with CLI (27 patients in AMG0001 group; 13 patients in placebo group). The safety evaluation was performed in 41 patients with CLI (28 patients in AMG0001 group, 13 patients in placebo group).

[Results of Analysis]

1) Primary Endpoint

AMG0001 group showed a significant improvement in pain at rest or ischemic ulcer. The improvement rate shown in the primary endpoint was 70.4% (19/24) and 30.8% (4/13) in AMG0001 group and placebo group, respectively; thereby, demonstrating a statistically significant difference between both groups ($p=0.014$).

Primary Endpoint (Improvement after 12 weeks)

Fontaine grade	group	Subject No.	Improved		95% CI	Difference	Analysis ¹⁾
			No	Yes			
	AMG0001 Group	16	8 (50.0)	8 (50.0)	24.7 ~ 75.3	25.0	p=0.388
	Placebo	8	6 (75.0)	2 (25.0)	3.2 ~ 65.1		
	AMG0001 Group	11	0 (0.0)	11 (100.0)	71.5 ~ 100.0	60.0	p=0.018
	Placebo	5	3 (60.0)	2 (40.0)	5.3 ~ 85.3		

(%) . 1)Fisher's direct analysis method

target: FAS

Grade Adjusted (according to Fontaine grade at enrollment)
(Primary Endpoint Variable)

Difference in Improvement rate	95% CI	Mantel Haenszel analysis
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38.7%	9.4 ~ 68.0	p=0.014 significance level: 0.02
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2) Other Endpoints

- Improvement rate of ischemic ulcer in patients of Fontaine IV in AMG0001 group was 100.0% (11/11 patients) while 40% (2/5 patients) in placebo group. The difference between both groups was 60% (p=0.018).
- Improvement rate of rest pain in patients of Fontaine III in AMG0001 group was 50.0% (8/16 patients) while 25.0% (2/8 patients) in placebo group. The difference between both groups was 25.0% (p=0.388).
- As for QOL, we used SF-36 system, which consists of 8 parameters; Physical Function, Role Physical, Bodily pain, General Health Perceptions, Mental Health, Role Emotional, Social Functioning, Vitality. Seven of 8 parameters, except for Role Physical, demonstrated a greater improvement in AMG0001 group than in placebo group. Especially, 2 parameters (Bodily Pain and Mental Health) were significantly improved in AMG0001 group as compared to those in placebo group (p=0.036, p=0.023).
- As for safety, HGF concentration in serum was not increased after the AMG 0001 treatment, so that we could confirm that AMG0001 with the dose regimen of this study did not affect the systemic circulation.
- As for adverse drug reactions (adverse events whose causal relationship with study drugs could not be ruled out), 28 cases were found in 18 patients in AMG 0001 group (28 patients) and 15 cases were found in 7 patients in placebo group (13 patients). The occurrence rate

was equal in both groups.

- As for serious adverse events, 8 cases were found in 6 patients in AMG0001 group (28 patients) and 4 cases were found in 3 patients in placebo group (13 patients). All cases were concluded to have either no causal relationship or less possible association with study drugs.

The results of this trial clearly prove the efficacy of AMG0001 for PAD patients, and AnGes believes that this is of significant importance to the industry.

However, AMG0001 is a novel molecule so that AnGes plans to carefully follow the safety of patients and will prepare for BLA (NDA) submission of AMG0001.

- Glossary -

SF-36 (MOS Short-Form 36-Item Health Survey)®

Short Form 36-Item Health Survey is a scientifically reliable and valid assessment scale developed for the measurement of quality of life (QOL) relating to patients' health. Currently, SF-36 system is translated in more than 50 languages and is widely used in the world.

SF-36® system consists of several questions to measure 8 health parameters. These 8 parameters for health conditions are "Physical function," "Role physical," "Bodily pain," "General health perceptions," "Mental health," "Role emotional," "Social functioning," and "Vitality."