

January 11, 2011
AnGes MG, Inc.

Medical Journal Publication of Data of US Phase II Study of Collatogene (HGF plasmid)

AnGes MG, Inc. is pleased to announce that data from the phase II clinical study of HGF plasmid Collatogene performed in the US was recently published in the Journal of Vascular Surgery, a prestigious journal in the field of vascular surgery.

This study is the second phase II study performed from 2005 to 2008 in the US by AnGes Inc., a subsidiary of AnGes MG, Inc. In 27 patients with critical limb ischemia for which there was no alternative therapy for revascularization, Collatogene 12 mg (4 mg \times 3 times: 21 patients) and placebo (6 patients) were compared. The main purpose of this study was to reconsider the method of administration of Collatogene. In the first phase II study, the site of injection of Collatogene in the lower limbs was the same in all subjects, whereas in this study, the site of injection was decided on an individual basis according to the subjects' site of ischemia (This method of administration is the same as that used in the Japanese clinical trials).

In this study, the entry of subjects was discontinued when half of the scheduled number of subjects were entered, and consequently no difference was noted in comparison to the placebo group in terms of improvement of ischemic ulcer as the primary endpoint, but significant improvement was observed in the Collatogene group compared to the placebo group in terms of lower-limb pain at rest and TBI (Toe Brachial Index) after 6 months of administration. On the other hand, in terms of safety, there was no difference in the incidence of adverse events between both groups, thereby confirming that Collatogene can be administered without any problems by the method of administration used in this study as well. It is believed that this data represents important results that may support the global US and Europe phase III study which is currently being planned.

The study results are published at

[http://www.jvascsurg.org/article/S0741-5214\(10\)01821-5/abstract](http://www.jvascsurg.org/article/S0741-5214(10)01821-5/abstract).

Meanwhile, there will be no effect of this publication on AnGes MG's business performance for the term ending in March 2011.