January 4, 2011 AnGes MG, Inc.

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Medical Journal Publication of Long-Term Data of Japanese Phase I/II Studies of Collategene (HGF plasmid) - Clinical Study for Peripheral Vascular Diseases in Osaka University -

AnGes MG, Inc. is pleased to announce that the long-term clinical research data on HGF gene therapy performed at Osaka University Hospital was recently published online in "Arteriosclerosis, Thrombosis and Vascular Biology," a prestigious journal in the field of vascular diseases including peripheral vascular diseases.

This clinical study was first in human study for Collategene. Collategene was intramuscularly administered twice in an ischemic region in the lower limb at an interval of 4 weeks in 22 patients with arteriosclerosis obliterans (ASO) or Buerger's disease who did not respond to conventional drug therapies and who was not suitable for revascularization.

From data obtained early after gene delivery (until 3 months later) in a small number of early-stage cases, it was already reported that administration of Collategene involves no safety problem (Morishita R et al, Hypertension 2004;44:203-209).

This article reports the safety and efficacy data obtained until 6 months after gene delivery in all of the 22 patients. In patients who were treated with Collategene, lower-limb pain at rest and ischemic ulcer were obviously improved in correlation with the elevation of ABPI (Ankle Brachial Pressure Index; a ratio of lower/upper limb blood pressure), which is the index for lower-limb hemodynamics, and this effect was observed continuously for 6 months or longer. This is an important result as a Proof of Concept of Collategene, a therapeutic drug for peripheral vascular diseases. There were no serious adverse drug reactions caused by administration of Collategene, thereby confirming a high level of tolerability.

The study results are published at: <u>http://atvb.ahajournals.org/cgi/content/abstract/ATVBAHA.110.219550v1</u>.

Meanwhile, there will be no effect of this publication on AnGes MG's business performance for this fiscal year.