Completion of Trial Subject Enrollment for the US Phase II Clinical Trial of HGF Plasmid for Peripheral Arterial Disease (PAD)

AnGes, Inc., a US subsidiary of AnGes MG, launched a Phase II clinical trial of HGF plasmid in patients with peripheral arterial disease (arteriosclerosis obliterans) in April 2003. The enrollment of the 100th subject, which is the initial target number of subjects in the present trial has been completed at this time.

The trial is administered to subjects currently being screened and the enrollment of all subjects in the trial is expected to finish in mid-June. As soon as the evaluation period after administration of each subject is completed, the Company will perform data analyses and conclude evaluations on the results of the trial.

HGF plasmid has the ability to generate the growth of new blood vessels. This neovascular effect is intended to be used for treatment of ischemic disease in which the lumen of the blood vessel is narrowed due to arteriosclerosis, and blood flow in the heart is impaired. As this genetic medicine operates in a different manner than conventional drugs, it is expected to be effective for people who do not sufficiently respond to conventional drug therapy or who cannot undergo surgery. AnGes has mainly been developing HGF plasmid with indications for both fields of PAD with decreased blood circulation in the lower limbs (obstructive arteriosclerosis and Buerger's disease) and ischemic heart disease (IHD) with impaired cardiac flow.

For the development of HGF plasmid, AnGes is now expecting to complete the enrollment of subjects for the US Phase II clinical trial in patients with PAD. Multi-center, double blind Phase III clinical trials are also being conducted in Japan. In addition, for the area of IHD, a Phase I clinical trial is moving ahead in the US. The AnGes group aims to develop HGF plasmid for both PAD and IHD concurrently in Japan and the USA.

AnGes has granted Daiichi Pharmaceutical Co., Ltd. the distribution rights for HGF plasmid in both PAD and IHD indications in Japan, the USA and Europe.