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AnGes MG, Inc.

Results of the US Phase I Clinical Trials with HGF Gene Plasmid for Ischemic Heart Disease (IHD)

AnGes MG, Inc. (AnGes) is pleased to announce that the Data Safety Monitoring Board (DSMB) for the IHD indication reviewed the interim safety data (3 months) and did not find any critical safety concerns in the US Phase I clinical trial.

HGF plasmid contains the gene for human Hepatocyte Growth Factor (HGF) which has angiogenesis effect. It could be the treatment for ischemic disease which is low blood flow caused by occlusion or narrowing of the vessels due to arteriosclerosis. As this drug has a different mechanism from conventional drugs, it expected to be effective for subjects who do not sufficiently respond to conventional drug therapy or who are poor candidates for revascularization. AnGes is developing HGF plasmid in subjects who have poor perfusion in the lower limbs, this is known as Peripheral Arterial Disease (PAD) which includes arteriosclerosis obliterans and Buerger's disease, along with subjects with IHD, who have poor perfusion in myocardium.

The primary objective of this Phase I clinical trial was to assess the safety of HGF plasmid in subjects with IHD. In general, healthy volunteers are used for Phase I studies to assess safety. However, as healthy volunteers are not appropriate to assess safety particularly for anticancer drug and gene therapy, Phase I trials for this kind of drugs are conducted using subjects with the target disease. In addition to that, this study used an investigational endocardial injection catheter to administer the HGF plasmid into the target ischemic lesion of myocardial. Thus nine severe IHD patients were enrolled in this study.

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