AnGes Submits NDA for HGF Gene Therapy

AnGes MG, Inc.(TSE Mothers:4563, http://www.anges-mg.com) has submitted its New Drug Application (NDA) to MHLW (Japan) for HGF Gene Therapy (INN: beperminogene perplasmid, Brand Name: Collategene) to treat Critical Limb Ischemia (CLI) in Arteriosclerosis Obliterans (ASO) and Burger's disease, on March 27, 2008.

HGF Gene Therapy is a product, where a gene which induces HGF protein is injected to the ischemic lesion, leading to the formation of new blood vessels through the effect of the HGF protein, which results in improvement of the ischemic symptoms.

AnGes has developed this product for peripheral arterial diseases (ASO and Burger's Disease), which occurs by decreased blood flow caused by narrowing of blood vessels as a result of arteriosclerosis, and ischemic heart disease.

This is a product with a novel mechanism of action different from existing products, so that it may also be effective to patients in which existing therapeutics were not effective, or, surgical treatments can not be pursued. As for safety, we are using naked DNA delivery method instead of viral vectors to transfect genes, so that there won't be any safety concerns often caused by viral vectors in case of gene therapies.

HGF is a gene therapy product originally developed in Japan through the research at Academia, and development went ahead in Japan first.

Since last June, when we got the positive results at the interim analysis of our Phase III study in Japan for ASO patients with CLI, we have prepared for submission, and are pleased to be the first company in Japan to submit an NDA for a gene therapy product.

AnGes is aiming to provide this product to patients also worldwide.

After approval, the brand name in Japan will be "Collategene". The name comes from the meaning of formation of "collateral vessels" by angiogenesis and improvement of ischemic symptoms by "gene therapy".