April 21, 2010
AnGes MG, Inc.

Medical Journal Publication of Data from
"Collategene" Phase III Clinical Study Performed in Japan

AnGes MG, Inc. is pleased to announce that clinical trial data from the phase III clinical study of HGF gene therapy product "Collategene" performed in Japan was published in "Gene Therapy (on-line version)", a prestigious journal in the field of gene therapies.

This trial was a multi-center, placebo-controlled, randomized, double-blind, comparative study in which Collategene 4 mg or placebo was intramuscularly administered into the ischemic site of the lower limbs twice, at a 4-week interval and followed by 8 weeks observation (treatment period: 12 weeks). The target patients had critical limb ischemia due to arteriosclerosis obliterans that were not applicable for revascularization and did not respond to conventional drug therapies. The primary endpoint "the improvement rate for pain at rest or ischemic ulcer size at 12 weeks" showed significant improvement in the Collategene group compared with the placebo group. And concerning safety, there were no characteristic serious adverse reactions to the drug under study, including the post administration 15 months long-term follow-up period, in which the Collategene group showed a high level of tolerability.
The study results are published at http://www.nature.com/doifinder/10.1038/gt.2010.51.

Regarding this publication, Ei Yamada, Ph.D., AnGes MG's President and CEO commented as follows. "The opportunities have been few for data from clinical studies performed in Japan to be published in leading journals. I believe that this recent publication in Gene Therapy is of great significance and stands as the proof of the international value of Collategene's clinical trial data."

Meanwhile, there will be no effect from this publication on AnGes MG's business performance for the term ending in December 2010.

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- Characteristics and Medical Significance of HGF Gene Therapy Product -

HGF is known to have potent angiogenic activity. HGF gene therapy is a product, whereby enables a gene that induces HGF protein to be injected in 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. This therapeutic drug uses naked DNA without any viral vectors, thus avoids risks derived from viral vectors. Additionally, unlike the mechanism of action of conventional drugs, the product improves the ischemic condition through angiogenesis, and therefore the product may become an innovative therapeutic drug expected to be effective in cases of intractable peripheral arterial disease or ischemic heart disease that does not respond to existing therapies.

- Glossary -

1. Gene medicine

A medicine, wholly, or partially comprising a genetic expression.

2. Hepatocyte Growth Factor (HGF)

A growth factor developed from hepatocytes; in addition to blood vessel regeneration, it initiates various processes necessary for tissue/organ regeneration during organ formation (organogenesis).

3. Peripheral arterial disease (PAD)

When peripheral blood vessels of the limbs become contracted, blood flow becomes insufficient; often seen in arteriosclerosis obliterans (ASO) and Buerger's disease.

To determine the severity of arteriosclerosis obliterans, the Fontaine classification is commonly used, where symptoms progress from grade I: no symptom, to grade II: intermittent claudication, grade III: pain at rest, and grade IV: lower-limb ulcer/gangrene. Particularly, grade III and grade IV are called "Critical Limb Ischemia", which is the most severe condition. If some kind of therapy is not adequately conducted, there is often no other choice but to amputate the extremity.

4. Ischemic heart disease (IHD)

IHD conditions are caused by relative lack of blood flow to the heart. Characteristic symptoms are angina pectoris accompanied by tightness in the chest and chest pains, and myocardial infarction caused by disorders of coronary blood vessels becoming completely clogged, and heart muscle tissue becoming ischemic.

5. Naked DNA

Our methodology of the HGF genetic medication uses genes spiraling in plasmid DNA (a naked DNA technology). Plasmid DNA alone may not be able to penetrate the cell membrane, it can, however, generate genes if injected intra-muscularly. This is the simplest method of non-viral gene transfection. This technology is extremely safe with no danger of contamination and cytotoxicity due to viral vectors.