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AnGes MG, Inc.

Long-Term Data of Japanese Phase I/II Trial of Collategene™ (DNA Plasmid with HGF Gene) Published in a Medical Journal - Gene Therapy Clinical Research in Peripheral Arterial Disease at Osaka University –

AnGes MG Inc. ("AnGes") is pleased to announce that the long-term results of its main clinical research project the HGF gene therapy with Collategene conducted at Osaka University Hospital were recently published in the online version of the prestigious journal in the field of vascular diseases, "Arteriosclerosis, Thrombosis and Vascular Biology."

This clinical research was the first human study for CollategeneTM (DNA plasmid with HGF gene). It was conducted in 22 patients with arteriosclerosis obliterans or Buerger's disease who are not amenable to revascularization surgery and conventional medical treatment. CollategeneTM was intramuscularly administered twice in the location of ischemia in the lower limb at a four-week interval. The safety and efficacy data of post six months of gene transfer have already been reported (Arterioscler Thromb Vasc Biol. 2011; 31: 713-720.)

In the article, the safety and efficacy data of post two years of gene transfer was reported. Among the patients who have been administered CollategeneTM, improvement was continuously observed against ABPI (Ankle Brachial Pressure Index) indicating the hemodynamic status, reduction of rest pain and reduction in the size of ischemic ulcer. Furthermore, the post two year results showed major amputation rate of 0% and mortality rate of 9.5% which can be considered better results compared with historical data reported in other studies. This data indicate that although angiogenesis function of HGF has disappeared after certain period, long-term efficacy of treatment with CollategeneTM can be expected for patients who are not amenable to conventional treatments. It is an important report which indicates CollategeneTM's function as a treatment of Peripheral Arterial Disease (PAD) and the efficacy against major amputation prevention and reduction in mortality rates that are the endpoints of global Phase III trial to be conducted later. In the view of safety, no severe adverse events caused by administration of CollategeneTM were observed, thereby confirming a high level of tolerability.

The abstract of study results are published at: http://atvb.ahajournals.org/content/early/2012/08/16/ATVBAHA.111.244632.abstract

This trend will have no effect on the business performance for the fiscal year of 2012.

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(Reference)

Gene Medicine

A drug which utilizes gene or a part of gene as active ingredient.

HGF (Hepatocyte Growth Factor)

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).

Peripheral Arterial Disease (PAD)

Narrowed or blocked peripheral blood vessels in the limbs cause ischemic condition in muscle and skin tissues, with the following symptoms: a feeling of paralysis, coldness, intermittent claudication, ulcer of lower limbs (thrombic disease) or rest pain. It includes arteriosclerosis obliterans and Buerger's disease.

Disclaimer: This is a translation of the news release posted in Japanese. In case of any deviations between the two language versions, the original document in Japanese shall take precedence.

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