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AnGes MG, Inc.

First Patient Dosed in Global Phase III Clinical Trials of HGF Plasmid for Critical Limb Ischemia

AnGes MG, Inc. (“AnGes”) announced that the first patient has been dosed in the global Phase III clinical trial of HGF Plasmid (AMG0001, Beperminogene Perplasmid, “Collategene“) for Critial Limb Ischemia (CLI).

As announced on October 6, the study started enrollment of patients in the beginning of October. The first patient was dosed on November 12, 2014 at an study site in the US after successfully completing the screening process. The Phase III study will evaluate the safety and efficacy of HGF Plasmid in approximately 500 subjects with CLI. The trials will be conducted in North America, Europe, and South America (15 countries) and the data will be collected for application to the US and European authorities. AnGes will continue to proceed with the global Phase III clinical trial by enrolling and dosing subsequent patients.

The global phase III clinical trial of HGF Plasmid

The clinical trial is a placebo-controlled, double-blind, randomized, and multi-center study to be conducted in approximately 500 patients with CLI in 15 countries across North America, Europe, and South America.

CLI and gene therapy with HGF Plasmid

CLI is a condition of peripheral arterial disease where severely reduced blood flow to the legs causes severe pain, ulcers or necrosis, and in the worst case, amputation of the limb becomes unavoidable. There are an estimated 500,000 patients of CLI in the US alone. There is no effective therapy for patients who are not suitable for current treatments such as endovascular interventions with balloon catheter or vascular bypass surgery. When injected into a patient‘s muscle, HGF gene medicine, being a plasmid DNA encoding the human Hepatocyte Growth Factor (HGF) gene is expected to form new blood vessels and improve blood flow to the affected limb.

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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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