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AnGes MG, Inc.

## **AnGes to Start Global Phase III Clinical Trials of HGF Gene Therapy for Critical Limb Ischemia in Europe**

AnGes MG, Inc. (“AnGes”) announces that it has completed the necessary procedures to commence the global phase III clinical trials of gene therapy with HGF Plasmid (AMG0001, Bepmerinogene Perplasmid, “Collatogene”) in 6 major European countries.

The Phase III study will evaluate the safety and efficacy of HGF plasmid in approximately 500 subjects with Critical Limb Ischemia (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. The enrollment of patients has already started in the US. The Clinical Trial Authorisation (CTA) Application\* submitted by AnGes has been accepted in 6 major European countries. AnGes will subsequently open the trial facilities and start patient enrollments in Europe.

\* The Clinical Trial Authorisation (CTA) Application has been submitted under the Voluntary Harmonisation Procedure (VHP) for 6 countries including England and Germany. The VHP system allows an application to receive a coordinated assessment for a clinical trial to be conducted in several European countries. For the other European countries, the applications are being processed individually.

### 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 HGF Gene Therapy

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 is no effective therapy for patients who are not suitable for

current treatments such as endovascular interventions 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. There are an estimated 500,000 patients of CLI in the US alone, and the potential market size is estimated to be 5 billion US dollars.

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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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