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AnGes MG, Inc.

Patient Enrollment Begins in Europe in the Global Phase III Clinical Trial of HGF Gene Therapy for Critical Limb Ischemia

AnGes MG, Inc. (“AnGes”) announced that the first European patient has been dosed in the global phase III clinical trial of gene therapy with HGF Plasmid (AMG0001, Beperminogene Perplasmid, “Collategene“) for treating critical limb ischemia (CLI). Patient enrollment, which first began in the U.S. in October 2014, has now started in Europe with the first patient enrolled and dosed in Hungary.

The phase III study will evaluate the safety and efficacy of HGF Plasmid in approximately 500 subjects with CLI in North America, Europe, and South America. It is a pivotal study intended to collect clinical data for marketing application to the U.S. and European authorities.

AnGes will move ahead with the global phase III clinical trial by enrolling and dosing new patients in other Eurpean countries and South America.

The global phase III clinical trial of gene therapy with HGF Plasmid

The clinical trial is a placebo-controlled, double-blind, randomized, and multi-center study. It will target approximately 500 patients with CLI in Europe, North America, and South America.

CLI and gene therapy HGF Plasmid

CLI is the severest condition of peripheral arterial disease in which the severely reduced flow of blood to the legs causes intense pain, ulcers, or necrosis. In the worst cases, the amputation of limbs becomes unavoidable. There is no form of effective therapy for patients for whom current treatments, such as endovascular interventions with a balloon catheter or vascular bypass surgery, are not suitable. When the plasmid DNA encoding human hepatocyte growth factor (HGF) gene is injected into a patient's muscle, it is expected to form new blood vessels and improve the flow of blood to the affected limb. There are an estimated 500,000 patients with CLI in the US alone, providing a potential market with an estimated value of 5 billion USD.

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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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