



October 6, 2014

AnGes MG, Inc.

## **AnGes Starts Global Phase III Clinical Trials of Collategene® for Critical Limb Ischemia**

AnGes MG, Inc. ("AnGes") announces that it has commenced the global phase III clinical trials of Collategene® with the enrollment of patients in the US.

The first patient was enrolled in the study on October 3, 2014 and began screening\*. Enrollment and treatment of subsequent patients will now commence.

The Phase III double-blind, randomized, placebo-controlled study will evaluate the safety and efficacy of Collategene® in approximately 500 subjects with CLI. Data will be collected for application to the US and European authorities. The trials will be conducted in North America, Europe, and South America (15 countries excluding Japan) over a period of approximately three years (from the first patient enrollment to the end of last patient visit), and submission of the Biologics License Application is targeted for as early as 2018 in the US, with applications in Europe to follow.

Critical Limb Ischemia is a condition of peripheral arterial disease where severely reduced blood flow to the legs develops severe pain, ulcers or necrosis, and in the worst case, amputation of the limb becomes unavoidable. There is no effective medicine for patients who are not suitable for current treatments such as endovascular interventions or vascular bypass surgery. When injected into a patient's muscle, Collategene®, a plasmid DNA encoding human Hepatocyte Growth Factor (HGF) gene is considered to form new blood vessels and improve blood flow to the affected limb. There are an estimated 500,000 patients of Critical Limb Ischemia in the US alone, and the potential market size is estimated to be 5 billion US dollars.

Ei Yamada, President and CEO, AnGes, says, "We have begun the final steps toward the approval of Collategene® as a treatment of CLI, which has been our core project since the company's establishment. Obtaining approval for Collategene® not only provides a new treatment option to patients suffering from CLI, but will also become a major source of revenue for AnGes. The realization of Collategene® is an important step towards our

company's vision of becoming a global leader in gene therapy.”

The effect of this event on AnGes' business performance for the fiscal term ending in December 2014 is included in the forecast published on the “Consolidated Financial Report for the Year Ended December 31, 2013” announced on February 7, 2014.

\*Screening: a process to evaluate whether a subject matches the eligibility of the clinical study protocol.

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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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