



June 20, 2016

AnGes MG, Inc.

## **AnGes Announces Amendment to the Global Development of HGF Plasmid for Critical Limb Ischemia**

AnGes MG, Inc. ("AnGes") announced its decision to amend the global development strategy of HGF Plasmid (AMG0001, Bepermingene Perplasmid) for the treatment of critical limb ischemia (CLI). Under the amended development strategy, AnGes terminates the currently ongoing Phase III clinical study, and implements a new plan intended to accelerate the development and minimize the development costs. The amendment is due to a financial consideration and not a safety concern on HGF Plasmid.

AnGes initiated the phase III global study of HGF Plasmid for CLI in October 2014. This study was designed to enroll 500 subjects in 15 countries throughout North America and Europe (Japan was not included in this study), and its goal was to collect clinical data for marketing application to the U.S. and European authorities. AnGes has reviewed the current state of the study and has determined that due to a much slower patient enrollment rate than originally anticipated, a longer period of time and greater costs would be required to complete the study under the current plan.

AnGes concluded that the amendment to the current development plan is necessary to avoid delays in the global development of HGF Plasmid and increases in costs. For this reason, AnGes made the decision to discontinue the ongoing Phase III study and to begin a new study, which would enable AnGes to complete the clinical study within a shorter time period. Under the new development strategy, AnGes expects to include the following changes in a new study such as 1) revision of primary endpoint to ulcer and pain (pain-at-rest) healings from the current Phase III endpoint, which is time to major amputation or all-cause death, and 2) selection of study sites experienced with CLI treatments in the U.S. to enroll suitable subjects.

This plan is intended to reduce costs and to ensure that the timing of our original plan for submission is maintained. AnGes intends to promptly begin discussions with the FDA regarding the new clinical study plans. The new plan shall be announced once the details are confirmed. In regard to the development of HGF Plasmid, no serious drug-related safety

issues have been reported in the clinical studies.

This amendment to the global development strategy does not affect the development of HGF Plasmid in Japan, which is being conducted separately from the global study.

Ei Yamada, President and CEO, AnGes, stated, "The termination of the ongoing Phase III study is a difficult but necessary decision made to accelerate the global development of HGF Plasmid and to minimize the development costs and timelines. I would like to thank all of the patients and physicians who supported the Phase III study. We will promptly design the details of the new development plan."

Due to this change, AnGes anticipates a reduction in development costs, and its impact on the financial performance for the fiscal period ending in December 31, 2016, is currently under review. AnGes will make an announcement if it becomes necessary to amend the business performance forecast as announced on February 5, 2016.

#### About AnGes

AnGes is a Japanese biopharmaceutical company that specializes in research, development and practical application of genetic medicines for diseases that are intractable or rare, and have no treatments available. The company's lead program is the gene therapy with hepatocyte growth factor (HGF) plasmid designed to improve blood circulation by regenerating blood vessels, for the treatment of critical limb ischemia. Additional information on AnGes is available at [www.anges-mg.com/en](http://www.anges-mg.com/en).

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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.*

AnGesMG, Inc. Corporate Communications TEL:+81-3-5730-2641, FAX:+81-3-5730-2635 <a href="http://www.anges-mg.com">http://www.anges-mg.com</a>
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