



May 30, 2014

AnGes MG, Inc.

### **Announcement Regarding Collatogene® Project in Japan**

Plans for a physician led clinical study of AnGes MG, Inc.'s ("AnGes") Collatogene® (DNA Plasmid with HGF Gene) for Critical Limb Ischemia (CLI) to be led by Osaka University Graduate School of Medicine were announced at a science and technology group meeting of the Ministry of Health, Labour and Welfare held on May 26, 2014.

The physician led study of Collatogene® for CLI will be led by Osaka University Graduate School of Medicine, and will utilize the advanced medical treatment system\*<sup>1</sup> B group in Japan under which clinical tests for DNA plasmid with HGF gene medicine for patients with severe ischemic limb are scheduled. AnGes will provide the test drug as well as data accumulated through past development.

AnGes aims to apply for approval of Collatogene® under the conditional approval system\*<sup>2</sup> in Japan, and will include the the results of the physician led study in the application.

\*1 The advanced medical treatment system in Japan allows for a combination of services covered by public health insurance and advanced medical technology (not covered by public health insurance) if safety and efficacy are assured. The advanced medical treatment system includes group A and B, in which group B applies to treatments utilizing unapproved or off-label (unapproved usage of) drugs or medical devices.

\*2 The conditional approval system is a new system to be introduced in Japan that allows an early and conditional approval of regenerative medicines including gene therapy.

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