

June 27, 2013

AnGes MG, Inc.

AnGes Inc. Submits the Protocol of Small-scale Study of Collategene® to NIH's RAC Review

AnGes MG, Inc. (AnGes) announced that its subsidiary, AnGes Inc., (Maryland, United States [US]) submitted the protocol for a small-scale study of Collategene[®] to the US National Institute of Health (NIH) to receive Recombinant DNA Advisory Committee (RAC) review. The small-scale study is a preliminary study for the Phase III study of Collategene[®] (DNA plasmid with hepatocyte growth factor [HGF] gene) for the treatment of critical limb ischemia (CLI).

As announced on May 23, 2013, AnGes submitted the protocol for the small-scale preliminary study to the US Food and Drug Administration (FDA). The purpose of conducting the small-scale clinical study is to examine the feasibility of the Phase III study of Collategene® for the treatment of CLI. Upon acceptance by the FDA, AnGes submitted the protocol to the NIH to receive RAC review.

The RAC review comprehensively evaluates research studies involving recombinant DNA research from scientific, medical, safety, ethical, and social aspects. By going through this review, the research studies are ensured by the NIH and widely recognized by specialists in this field.

"After receiving RAC review, which ensures our protocol has no scientific, safety, or ethical issue of concern, we would like to start the small-scale clinical study, and promptly proceed with preparations for the global Phase III study to deliver treatment to patients with severe limb ischemia who currently have no treatment option," said President and Chief Executive Officer of AnGes, Ei Yamada.

This event has no effect on business performance for the fiscal year 2013.

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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.

AnGes MG, Inc.
Corporate Communications
TEL: +81-3-5730-2641, FAX: +81-3-5730-2635
http://www.anges-mg.com