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AnGes MG, Inc.

Announcement of Results of Phase III Clinical Trials of HGF Gene Therapy in Japan

AnGes conducted an interim analysis of the PIII data using HGF Gene (AMG 0001) for Critical Limb Ischemia (CLI) in Japan, and is pleased to announce that remarkable improvement was observed in the AMG0001 group compared with the Placebo group.
Yesterday, an IDMC (Independent Data Monitoring Committee) was held, and now that the efficacy of AMG0001 is confirmed, the committee recommended to stop this trial in order to prevent potential ethical issues against the placebo group subjects. AnGes has accepted this advice today and decided to stop this trial. From now on, AnGes will closely communicate with governmental agencies and prepare for NDA filing.

Outline of Study Results

This trial is a randomized, placebo-controlled, double blind study for CLI subjects using AMG 0001.

In this efficacy evaluation, 40 subjects with CLI were evaluated. 27 subjects received AMG0001, and were compared with 13 placebo subjects. (The AMG0001 group received 8mg (4mg x 2) of AMG0001.)

The primary endpoints, which is, improvement of rest pain ((VAS (Visual Analog Scale)) or ischemic ulcer size, at 12 weeks post dosing, showed 30.8% improvement in Placebo group and 70.4% improvement in AMG0001 group and verified statistically significant difference (p=0.014)

As for safety, 41 subjects (AMG0001: 28 subjects, Placebo: 13 subjects) were evaluated.
Adverse drug reaction were equally distributed between AMG0001 group and placebo group.
There were 8 SAEs in 6 subjects in the AMG0001 group (peripheral ischemia, cerebella infarction, post procedural hematoma, prostate cancer, bladder perforation, acute renal failure, peritonitis, bacterial pneumonia). However, causality due to AMG0001 was estimated none or low.

In Placebo group, there were 4 SAEs in 3 subjects (2 embolism, toe gangrene, pain in thigh).

All SAEs out of all studies using AMG0001 were evaluated by the DSMB (Data Safety Monitoring Board) and it was concluded that, as of today, there is no major safety concern related to AMG0001.

While significant improvement was confirmed based on the efficacy evaluation, as AMG0001 is a highly novel therapeutic, AnGes will continue development by carefully following the safety.