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AnGes MG, Inc.

AnGes MG, Inc. Releases the Results of the US Phase II Clinical Trial with HGF Gene Plasmid for PAD (Peripheral Arterial Disease)

The results of the US Phase II clinical trial ("HGF-STAT Trial") were presented on June 3 at the Society for Vascular Medicine and Biology held in Philadelphia, PA.

The HGF-STAT Trial is a Phase II clinical trial using HGF gene plasmid, which is a randomized, double-blind, placebo controlled trial of intramuscular injection of HGF gene plasmid for the treatment of Critical Limb Ischemia ("CLI").

Patients with CLI who were poor candidates for other revascularization due to anatomy, poor conduit or medical comorbidities were enrolled into this trial. Patients were randomized and received 3 treatments consisting of 8 injections at Day 0, 14 and 28.
For each group, the total dose of HGF gene plasmid was 0mg (Placebo), 1.2mg (Low Dose), 8mg (Middle Dose), or 12mg (High Dose).

Efficacy was evaluated in 93 patients out of 104, and safety was evaluated in all 104 patients enrolled.
As for efficacy, analysis in the overall efficacy population showed no statistical significance, however, in a subgroup analysis, the Foot TcPO2 (transcutaneous partial pressure of oxygen) in the High Dose group increased statistically significantly compared to Placebo. Thirty nine percent of patients in the Placebo group, 57% in the Low Dose, 67% in the Middle Dose and 80% in the High Dose had a TcPO2 above 30mmHg at 6 months after the treatment.
As for ischemic ulcer, although not statistically significant, improvement was seen in the HGF gene plasmid treated groups compared to the Placebo group.

As for safety, there was no significant difference among the groups.

In conclusion, intramuscular injection of HGF gene plasmid suggests the potential to improve perfusion in patients with CLI. This treatment appears to be safe and well tolerated by patients.