

ViroMed Co., Ltd.

1510-8 Bongcheon-dong, Kwanak-gu, Seoul 151-818, Korea/http://www.viromed.co.kr

Non-technical Abstract

Peripheral arterial disease (PAD) is a common disorder usually caused by decreased blood flow to the legs, resulting in ischemic limb disease. Critical limb ischemia is a condition of severe arterial obstruction due to advanced PAD, associated with breakdown of the skin or pain in the lower limb at rest. The natural history of critical limb ischemia has been well documented to typically have a downhill course, frequently leading to the amputation of the affected limb.

Bypass surgery can be recommended for some subjects; however surgery involving small-size arteries are often unsatisfactory due to a high failure rate. Many subjects face amputation of their limb as the sole therapeutic option for the severe symptoms of critical limb ischemia especially when bypass surgery fails to improve symptoms. Psychological testing of such subjects typically shows results that measure quality-of-life that are similar to those of subjects with terminal cancer. It is estimated that about 150,000 subjects per year require lower-limb amputations for ischemic diseases in the United States alone. Consequently, there is an urgent need for novel treatment strategies for subjects with critical limb ischemia.

VM202, a DNA plasmid expresses human hepatocyte growth factor (HGF), has demonstrated potential for stimulating blood vessel growth in the legs of animals. A similar plasmid, VMDA-3601, that expresses a different protein, vascular endothelial growth factor (VEGF₁₆₅), was studied for the indication of PAD in a phase I clinical trial in Korea sponsored by ViroMed Co. Ltd. and is currently under phase II investigation. An increase in the number of vessels and reduction in pain were observed in 7 out of 9 subjects in the phase I trial. The drug was well-tolerated.

This proposed trial is entitled, "A Phase I, Dose-Escalation, Single Center Study to Assess the Safety and Tolerability of VM202 in Subjects with Critical Limb Ischemia". The study will consist of approximately 12 subjects who will receive VM202 as an intramuscular injection in 2 doses with a 2-week interval between the injections.

ViroMed will use the results of the trial to design a phase II clinical study.