

March 24, 2011  
AnGes MG, Inc.

Medical Journal Publication of Results of  
Study on Collategene (HGF gene therapy product) in Japan  
- Data of Open-Label Study Targeting Buerger's Disease -

AnGes MG, Inc. is pleased to announce that the data of an open-label study of the HGF gene therapy product "Collategene" for Buerger's disease (hereinafter, this study) was published in the April 2011 issue of *International Angiology*, a specialty journal in the field of vascular research.

This study was a clinical trial conducted in Japan around the same time as the phase III study for arteriosclerosis obliterans (ASO) (*Gene Therapy* (2010) 17, 1152-1161). In this study, safety and efficacy were investigated in 10 Buerger's disease patients with critical limb ischemia, who were observed for 12 weeks after intramuscular administration of Collategene. Buerger's disease is a rare disease designated as an intractable disease, for which treatment methods, etc. have been studied by the "Research Committee of Intractable Vasculitis Syndrome," a MHLW research group. Treatment of Buerger's disease with Collategene was adopted as one of their research themes, and this study was conducted by researchers of the group.

In the results of the study, obvious reduction in ulcer size was seen in 6 (66.7%) out of the 9 subjects who were evaluated, and complete disappearance of the ulcer evaluated was seen in 5 subjects, in terms of the improvement rate of ischemic ulcer as the primary efficacy endpoint. In regards to safety, there were no problems, such as serious adverse events, caused by the administration of Collategene. These results suggested the possibility of being able to provide a new treatment method for Buerger's disease, for which no secure treatment methods have been established, and the results may be an important achievement in considering the development of the product as an orphan drug in the future.

The study results are released at:

<http://www.minervamedica.it/en/journals/international-angiology/article.php?cod=R34Y2011N02A0140>

Meanwhile, there will be no effect of this trend on AnGes MG's business performance during the current fiscal year.

- Glossary -

Buerger's disease

Since the disease was first reported by Leo Buerger, it was named Buerger's disease (English or German pronunciation) after the reporter. It is sometimes called thromboangiitis obliterans. The disease causes obstruction in peripheral blood vessels of the limbs, thereby resulting in ischemic symptoms (hypoxic symptoms in tissues caused by insufficient supply of blood) in the limbs or fingers/toes. Patient's subjective symptoms include: coldness, numbness, or pallor of the fingers/toes, intermittent claudication (when walking over a long distance, leg pain occurs and walking becomes difficult, but after a rest, pain subsides and walking becomes possible), severe pain (pain at rest), and formation of ulcers (a deficiency of the skin), eventually leading to necrosis. These symptoms may occur in sequence or an ulcer may be formed in a fingertip, etc. from the beginning. Inflammation may also occur in hand or foot veins, thereby causing a flare or pain along the veins (migrating phlebitis).

The cause of its onset is unknown, but the disease is considered to be attributable to inflammation of peripheral blood vessels of the limbs (angiitis). It is known that cigarette smoking is strongly related to its onset and exacerbation, and it is said that almost all of the patients have a history of smoking including passive smoking (a situation where even a non-smoker is indirectly in a state of smoking because there are smokers around).

(Source: Website of Japan Intractable Diseases Information Center [as of March 2011])