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AnGes MG, Inc.

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Report on Long-Term Data of Collategene (HGF plasmid)
- Japanese Phase III Study for CLI -

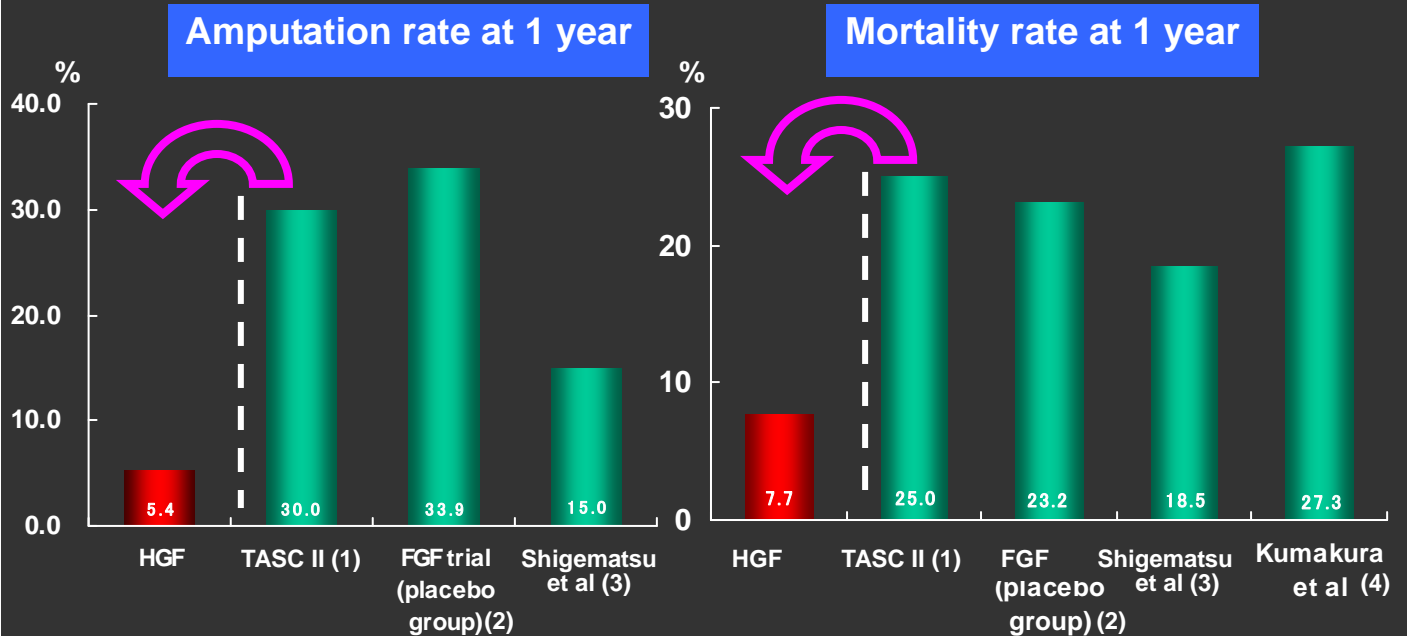
AnGes MG Inc. is pleased to announce that the long-term data of the Japanese phase III study of Collategene (HGF plasmid) for CLI (Critical Limb Ischemia) were reported today by the research group of Osaka University at the 18th Scientific Meeting of the Japanese Vascular Biology and Medicine Organization which is currently being held in Osaka (December 1 - 3, 2010).

The placebo-controlled, randomized, double-blind, comparative trial for ASO patients presenting CLI (hereinafter, this study) was started as a multicenter study in 2004. From the results, it was already reported that the superiority of the Collategene group versus the placebo group was confirmed in terms of the improvement of ischemic ulcer or pain at rest 3 months after the initial gene delivery, which was the primary endpoint, and that there is no problem in terms of safety (Shigematsu H et al, Gene Therapy 2010:17:1152-61).

In this study, long-term follow-up was performed for 3 years after gene delivery. It is said that the rate of lower limb amputation after 1 year in patients with CLI is about 30% in general, but the results of the study showed very low rates of lower limb amputation after administration of Collategene: 5.4% after 1 year, 5.4% after 2 years, and 9.2% after 3 years. Additionally, the mortality rate was 5.1% after 1 year, 15.7% after 2 years, and 26.6% after 3 years, showing favorable results. On the other hand, in terms of safety, there were no clinically significant adverse events that were strongly suspected of being related to gene therapy.

From the above, Collategene can be expected to produce favorable results also in the long term for cases of CLI that cannot undergo revascularization and that have not been improved by medical therapies.

Both the Amputation Rate and Mortality Rate were Low in CLI Patients Treated with HGF Plasmid (Comparison with Historical Control)



(1)Norgren L., et al. Inter-society consensus for the management of peripheral arterial disease (TASCII). Eur J Vasc Endovasc Surg, 2007; 22, S1-S70

(2)Nicol S et al. Mol Ther. 2008;16(5), 972-978.

(3)Shigematsu H et al. Therapeutic research 1992; 13 (10), 181-191.

(4)Kumakura H et al. J Vasc Surg 2010; 52:110-117.