January 8, 2003
AnGes MG, Inc.

IND application approved for HGF genetic medicine treating peripheral arterial diseases

Our U.S. subsidiary submitted an IND (Investigational New Drug) application for HGF genetic medicine treating peripheral arterial diseases (ASO) to begin clinical trials - it was approved by the U.S. F.D.A. Our group is thus going to be the first Japanese enterprise to perform clinical trials in the U.S.

The HGF genetic medicine regenerates the blood vessels to improve the condition of patients with alveoli clogged due to arteriosclerosis and similar blood circulation disorders. Application of the present medicine is principally different from all conventional drugs, enabling effective treatment in cases when general pharmacological therapy is insufficient, while surgery might not improve a patient's condition. We are developing medication mainly to treat PAD patients with progressing blood circulation disorders of lower limbs (arteriosclerosis obliterans, Buerger's disease), as well as those with progressing arteriosclerosis affecting blood circulation in the heart (ischemic heart disease, myocardial disorders).

The present approval by the FDA is the permission to conduct the second phase of clinical trials with PAD (ASO) patients as (in principle) the clinical research with human subjects has already been conducted at the Osaka University. We are thus proceeding with the second phase of our clinical trials in the U.S.

Marketing / distribution of the HGF genetic medicine in Japan, Europe and the U.S. for both, PAD and CAD, will be handled by DaiIchi SeiYaku (Dai Ichi Pharmaceutical) Co., Ltd.