1-CS-4 Company-Organized Symposium

Investigator-Initiated Clinical Trial of HGF Plasmid Product

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It has been known that hepatocyte growth factor (HGF) is produced along with hepatic and renal disorders and promote regeneration of injured organs through the proliferative effects on (1) vascular endothelial cells, (2) myocardial cells, and (3) lymphatic endothelial cells.

The mechanism of action of the HGF plasmid product is as follows; HGF plasmid is introduced by injection into skeletal muscle/myocardium, HGF protein is released outside muscle cells via the transcriptional /translational process within muscle cells, the angiogenesis and lymphangiogenesis though the mechanism of (1), (2), and (3) result in an improvement of symptoms of chronic obstructive arteriosclerosis, heart failure, and lymphoedema with amelioration of blood and lymphatic fluid circulation.

For the angiogenesis in the lower limbs, the data from the investigator-initiated clinical research at Osaka University (P1/2), company-sponsored clinical trials (P3), and the investigator-initiated clinical research by Advanced Medical Care B (P3) were used for the new drug application. For the angiogenesis in the heart, the investigator-initiated trial (P1) of Osaka University was conducted. For the lymphangiogenesis, the investigator-initiated trial (P2) of Asahikawa Medical University as well as the company-sponsored trial (P 1/2) are ongoing.

For development of products for treatment of rare diseases, as examples of industry-academia cooperation, we will introduce how we prepared for implementation of each investigator-initiated clinical research and investigator-initiated clinical trials, as well as what kinds of issues are there and how we have dealt with these issues to solve them.