

Green Cross begins clinical trials for hepatitis drug

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Singapore: South Korean biopharmaceutical company, Green Cross recently announced that it has received approval from the Ministry of Food and Drug Safety (MFDS) for its phase I clinical trial plan for "Hepabig-gene", a recombinant gene therapy, for treatment of the chronic hepatitis B virus (HBV).

Hepabig-gene has a potential to reduce HBV infection in liver transplant patients. The company had carried out clinical studies to evaluate the safety and efficacy of the Hepabig-gene on liver transplant patients who had underlying medical conditions of HBV infection.

According to Green Cross, the product has higher purity levels than existing plasma-based products and is more capable of neutralizing HBV. Therefore smaller doses are required over a shorter period compared with previous plasma-based products.

An official from the Green Cross said, "Until now, no country or company in the world has succeeded in the commercialization of a gene recombinant hepatitis B antibody treatment. So, Hepabig-gene is highly likely to be the world's first gene recombinant hepatitis B antibiotic medicine, if it is proven safe and effective."

Nearly 350 million people worldwide are suffering from HBV infection. Chronic hepatitis B patients are at considerably at a higher risk for the development of cirrhosis and hepatocellular carcinoma. Liver transplants are the only treatment option for such patients.