

Translation

Chronic Hepatitis C Treatment, Pegasys[®], and Antiviral Drug, Copegus[®], Designated for Priority Review by Ministry of Health, Labour and Welfare for the Indication of Compensated Liver Cirrhosis Related to Hepatitis C

February 1, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. (hereafter "Chugai") [Head Office: Chuo-ku, Tokyo. President: Osamu Nagayama] announced today that the Japanese Ministry of Health, Labour and Welfare (MHLW) designated a treatment for chronic hepatitis C (CHC), Pegasys[®], trade names: "Pegasys[®] S.C. 90 µg" and "Pegasys[®] S.C. 180 µg" (generic name: peginterferon alfa-2a) (genetic recombination) (hereafter "Pegasys[®]") and an antiviral drug, Copegus[®], trade name: "Copegus[®] 200 mg tablets" (generic name: ribavirin) (hereafter "Copegus[®]") as priority review subjects on January 13 following an application filed on October 25, 2010 with the MHLW seeking additional approval for the indication, "improvement of viraemia associated with compensated liver cirrhosis related to CHC".

The application for additional indication was made based on the domestic phase II/III clinical study, which was conducted on patients with compensated cirrhosis related to CHC. In the partial-blind comparative study, which randomized patients with compensated cirrhosis related to CHC to two parallel groups, combination therapy of Pegasys[®] and Copegus[®] vs. treatment-free group, the efficacy and safety of the combination therapy of Pegasys[®] and Copegus[®] in comparison with the treatment-free group were confirmed.

In patients with compensated liver cirrhosis related to CHC, chronic inflammation of the liver progresses finally leading to a serious outcome of hepatic failure or hepatocellular carcinoma. In Japan, the current medical treatment for improvement of viraemia in CHC patients with compensated cirrhosis is limited to a thrice weekly single-agent therapy with interferon. Therefore, a once weekly combination therapy of peginterferon and ribavirin is desirable as a new option, as it was in the case of improvement of viraemia associated with CHC, and is expected to reduce patients' physical and mental burden.

The indication of "improvement of viraemia associated with CHC" was approved for Pegasys[®] in 2003, and the combination therapy of Pegasys[®] and Copegus[®] for the indication was added in 2007. Both of them were designated as priority review subjects. Also, in addition to the indication of "improvement of viraemia associated with compensated cirrhosis related to

CHC ", an application for the indication of "the improvement of viraemia associated with chronic hepatitis B" has been filed on January 27 2011, and is now under examination.

Chugai will make best efforts for the early approval of the combination therapy of Pegasys® and Copegus® for " improvement of viraemia associated with compensated cirrhosis related to CHC" an area with a high unmet medical need, so that the therapy becomes available for the patients as early as possible.